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Implant Exposure after Immediate Reconstruction for Breast Cancer

Alfred Fitoussi*[a,b], Helene Charitansky[c], Fabien Petitperrin[b], Benoit Couturaud[b]

[a] Centre Du Sein, Paris, France
[b] Curie Institute, Paris, France
[c] Department of surgery, Centre Claudius Regaud, Toulouse, France

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ABSTRACT

Background: The technique most frequently employed for breast reconstruction, either immediate (IBR) or delayed (DBR), is the insertion of a prosthesis. The placement of a foreign body always carries the risk, albeit small, of peri-prosthetic infection and exposure of the implant that necessitates its removal, signaling the temporary or permanent failure of the reconstruction.

Methods: We retrospectively analyzed data of 738 consecutive patients immediate implant-only breast reconstructions between 1989 and 2005 in order to evaluate the contributing factors of failure.

Results: Our statistical analysis identified 3 statistically significant risk factors of implant extrusion: irradiation (P = 0.01), post-operative chemotherapy (P = 0.03), and the use of non- Becker expanders (P = 0.02).

Conclusions: It is important, especially for the multidisciplinary breast cancer team members, to be aware of these factors in order to make the optimal decision for immediate reconstruction after mastectomy and the suggested techniques. The patients should also be aware, as part of a shared medical decision, of the risks and their frequency before accepting IBR.

Introduction

Reconstruction, whether immediate or delayed, after mastectomy for breast cancer is most commonly performed using breast prostheses.[1] There are many techniques and improvements, as much on the technical side as with the materials used. However, the risk of infection of the implant and the necessity to remove the implant remains a permanent concern to the surgeons, independent of the psychological impact and medico-legal consequences for the patients.[2,3]

The literature has little on this subject, but confirms that implant-based reconstruction may be occasionally maintained once infection has supervened.[4-7] Further surgical attempts at reconstruction after an infection, in those who agree, tend to require musculocutaneous flaps, which come at the cost of additional donor scars.

We retrospectively analyzed the records of 738 patients between 1989 and 2005 and the different treatments received in order to analyze the possible contributing factors of prosthetic extrusion/removal.

Methods

The records of 738 patients who underwent implant-based immediate breast reconstruction

Address for correspondence:
Alfred Fitoussi, MD
Address: Centre du sein, 18 rue Pierre et Marie Curie, 75005, Paris, France
Tel : +331 44402002
Email : alfred.fitoussi@gmail.com

(IBR) between 1989 and 2005 were analyzed retrospectively. The data collection was consecutive and involved a single institute although the surgeons were of variable experience levels (including trainees and consultants).

Inclusion criteria

All patients who were candidates for mastectomy and immediate breast reconstruction were included in the study. Indications for performing IBR were as follow: 1) primary treatment of breast cancer by mastectomy when adjuvant radiotherapy was not planned post-operatively, according to our institutional protocols. These patients received radio- or chemotherapy, if the final histopathological diagnosis required a change to the original therapeutic plan. 2) Recurrence after breast conserving therapy (BCT), when clinical examination confirmed the indication of implant-based reconstruction without musculocutaneous flaps. All these patients had previously received irradiation as part of their BCT.

Mastectomy was performed with the preservation of the maximal possible skin, whilst being oncologically secure. The reconstruction itself comprised a prosthesis completely covered by muscles; both pectorals and the serratus anterior.[8] In some cases of recurrence following BCT, the quality of the pectoral muscles did not allow complete implant coverage. The use of an abdominal advancement flap is becoming more and more frequent, both to cover the prosthesis and to allow creation of a high quality infra-mammary fold.

Study variables

The study variables included age, menopausal status, clinicopathological variables (surgical indications, histological results, and adjuvant therapy indications, if necessary), surgery-related factors (number of operations on the same breast before reconstruction, scars, skin sparing, type of implant, number of devices change, and complications), and data concerning implant removal (clinical presentation and symptoms, detected microorganisms, biologic abnormality, medical therapy for infection, immediate and later surgical treatments, and possibly the refusal of new reconstruction by the patient).

Statistical analysis

The Kaplan-Meier test was used to analyze the data. The follow-up period was defined from the day of mastectomy and immediate breast reconstruction. The event was considered as the first implant removal due to complications such as fever, threatened or actual extrusion, and suspicion of peri-prosthetic infection. Patients who experienced no events were censored, if the implant was preserved. A desired event was defined as the implant removal only in patients who were operated without using the flap. Curves were compared with univariate analysis by Logrank test. The role of successive prosthesis number on the removal device risk for complication was studied by Cox model.

A Cox model with Forward method was used to study the independent role of each clinical and non-clinical variables, in particular, surgical techniques, on the device removal risk due to complications.

Results

Patient demographics

A total of 738 patients were enrolled in the current study. The median age of the patients was 48 years (range: 21 – 75 years) with a median follow-up of 75 months (69-83). The majority of the patients were pre-menopausal (68.4%) and the body mass index (BMI) was less than or equal to 20 kg/m^2 in 202 (28.6%) participants. A total of 700 (94.8%) patients who underwent reconstruction were newly diagnosed with breast cancer and the rest of the participants (38) had previously undergone BCT and were diagnosed with recurrence. The median hospital stay was 7 days (range: 4 – 37 days).

Histopathological findings

The most common histological type of the tumor was DCIS (69.8%). According to the TNM classification, a total of 501 (71.8%) patients were diagnosed with in situ (T0) tumor, 94 (13.5%) had a tumor less than 2cm in diameter (T1), 57 (8.2%) had T2 tumors, and 11 (6.6%) patients were diagnosed with tumors larger than 5cm (T3). Details could not be found for 35 (4.7%) patients. The nodal status was known in 692 of the 700 patients treated for a newly-diagnosed cancer of whom 646 (93.3%) were classified as N0, 42 (6.1%) as N1a, and 4 (0.6%) as N1b.

Overall, taking into account the patients with recurrent tumors, 489 (66.3%) had some forms of surgical procedure prior to breast reconstruction. A change in the status between the pre-operative biopsy and definitive histopathological result caused a modification (upgrade) in the planned therapeutic strategy in 125 patients. All of the patients received radiotherapy and 85 (68%) of them received chemotherapy.

Reconstructive technique

In 486 (65.8%) mastectomy cases, the surgeons were able to preserve the breast skin and additional plastic surgical techniques were employed in 138 (18.6%). The plastic techniques were the round block (57%) and inverted-T incision pattern (63%). A synchronous symmetrizing procedure was performed on the contra-lateral breast in 512 (69.4%) patients.

Axillary node harvest was performed during the

reconstruction procedure in 660 patients (89.5%) with a mean node number of 10 (range: 0 – 40). Four implant types were used during the study period: saline (n = 289), silicone filled prostheses (n = 244), and Becker (n = 140) and non-Becker expander-prostheses (n = 65).

Adjuvant therapy

Forty-two patients had previously received radiation therapy before IBR (5.7% of the patients), predominantly for recurrence of the initial cancer (n = 38) and for hematological malignancy (lymphoma). Adjuvant radiotherapy to the chest wall and/or nodal fields was given to 125 patients (16.9%). Neoadjuvant chemotherapy was used either during the primary treatment of those with recurrence (n = 34; 4.6%) or in cases with *de novo* cancers (n = 85; 11.5%). Overall, 78% of the patients received no radiotherapy and 85.4% received no chemotherapy before and after surgery.

Implant removal

Implant removal was necessary in 29 cases (3.9%) for either infection or extrusion. It occurred mostly within 2 months of surgery in 17 patients (57%). The implants were removed for the other 12 cases in different times after the operation beyond 8 weeks. The last one was done 121 months after surgery.

Reasons for implant removal included pyrexia (14 patients), abscess (10 patients), and lymphatic collection (5) with some patients experiencing a combination of symptoms.

The implant was exposed in 15 cases, of whom 9 were secondary to cutaneous necrosis and 6 secondary to delayed healing.

All in all, implant removal was required in 29 patients: for skin necrosis or delayed healing (20), in which, 6 had signs of associated infection. In seven patients, the implants were removed due to infection without skin necrosis. Two remaining patients underwent implant removal due to hematomas.

Clinical features of infection included pain, erythema and local heat, pyrexia, and purulent discharge.

Through univariate analysis, three factors (implant type, radiotherapy and chemotherapy) were identified as being associated with implant removal which remained significant in multivariate analysis. The use of a non-Becker expander gave a relative risk (RR) of removal of 3.2 (P = 0.02). Either pre- or postoperative radiotherapy was a statistically significant risk factor for implant removal (P = 0.01) and the risk was greater when irradiation was administered after reconstruction (P = 0.004 in multivariate analysis) with an RR of 3.2. Postoperative chemotherapy also appeared to affect implant removal (P = 0.03) (Table 1). On the other hand, postoperative chemotherapy also appeared to affect implant removal (P = 0.03) (Table 2).

Table 1. Rate of prosthesis removal for complications with respect to irradiation

	Rate (%) at 1 year	Rate (%) at 5 years
No radiotherapy	2.09 (0.91-3.25)	2.59 (1.22-3.93)
Pre-operative radiotherapy	4.76 (0-10.99)	4.76 (0-10.99)
Post-operative radiotherapy	5.83 (1.54-9.93)	7.64 (2.7-12.31)

Table 2. Rate of implant removal for complications with respect to chemotherapy.

	Rate (%) at 1 year	Rate (%) at 5 years
No chemotherapy	2.39 (1.18-3.57)	2.84 (1.48-4.18)
With chemotherapy	5.56 (1.13-9.78)	7.50 (2.36-12.38)

The factors which were not associated with an increased risk of implant removal included age (P = 0.7), a BMI of less than 20 (P = 0.2), the incision pattern (P = 0.6), skin conservation (P = 0.6), synchronous axillary dissection (P = 0.6), prior surgery (P = 0.6) and implant exchange (P = 0.6).

In 276 patients whose implants were removed, another implant was inserted in the same operation. The number of implant changes was not found to be significantly related to implant removal (P > 0.6). The majority, i.e. 463 patients (62.7%), with only one implant and those with multiple implants are summarized in Table 3.

Table 3. Total prosthesis per patient according to the number of the implants at the time of complication

	Number of prosthesis at the time of complication				
Total prostheses per patient	0	1	2	3	Total
1	443	20	0	0	463
2	219	4	3	0	226
3	39	1	0	1	41
4	7	0	0	0	7
5	1	0	0	0	1

Surgical management of patients that underwent implant removal

A total of 29 patients had their prostheses removed for non-aesthetic complications. Preservation of the reconstruction was performed in 7 (24%) cases either through immediate exchange of the prosthesis (n = 3), autologous flap alone (n = 2), or combined implant-flap conversion (n = 2). A total of 22 (76%) patients underwent implant removal, simple lavage and drainage without immediate replacement or flap reconstruction. Of these, 7 underwent further reconstruction as a delayed procedure: implant-based (n = 2), autologous flap alone (n = 4), latissmus dorsi flap (n = 3), and one transverse rectus abdominis myocutaneous flap (TRAM flap) or combined implant-flap conversion (n = 1). Thus, 15 remained ultimately without a reconstruction (15/728 = 2.1%), 7 patients refused to undergo further surgery and in 8 patients the data were not available.

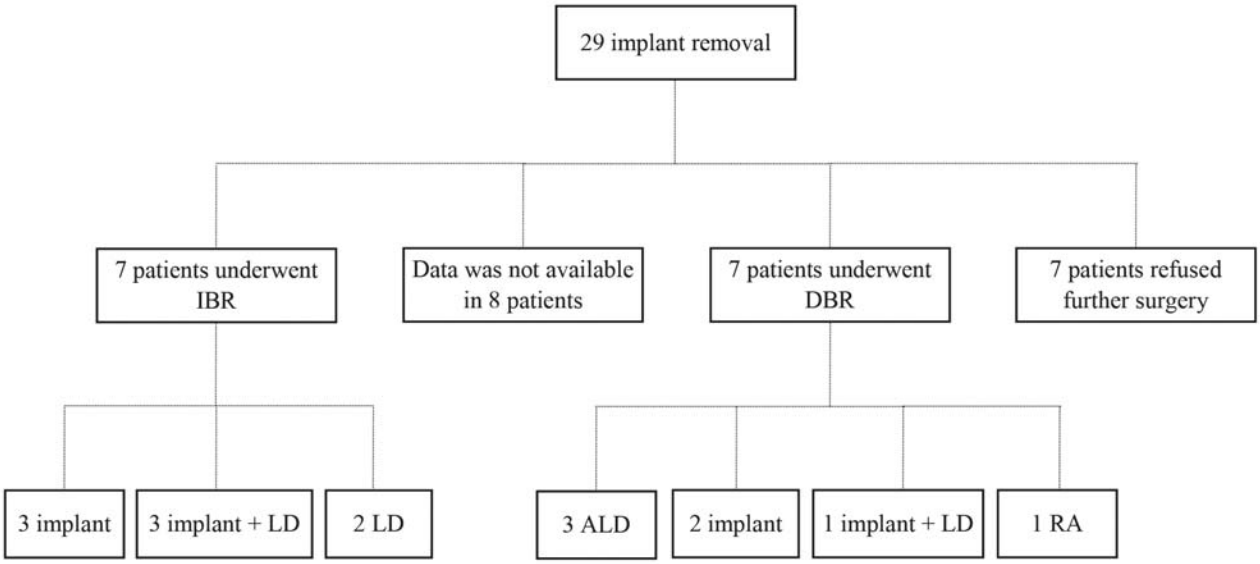

Figure 1. Summary of ultimate outcome of patients who required implant removal (IBR; immediate breast reconstruction, DBR; delayed breast reconstruction, LD; latissimus dorsi flap, ALD; autologous latissimus dorsi flap, RA; rectus abdominis flap)

Discussion

Our institutional protocols recommend an IBR in all circumstances where adjuvant therapy is not expected postoperatively. This is based on two fundamental principles: 1) avoiding a delay in adjuvant therapy as a consequence of either delayed healing or any other surgical complications and 2) the desire to not compromise the aesthetic result of reconstruction through irradiating a prosthesis due to the well-known risk of capsular contracture. Immediate implant-based breast reconstruction comprises approximately 50% of IBR at our institution.

In the current study, definitive histological results differing from preoperative diagnoses caused the unplanned addition of adjuvant therapy in 38.5%: chemotherapy in 15.6% and irradiation in 22.9% of cases after implant reconstruction. Patients must therefore be informed of this potential. In our series, 38 patients with recurrence accepted implant-only IBR, refusing any flap because of the additional donor scar. Clearly, the risk of postoperative complications, including delayed healing, implant extrusion, and ACC must be clearly explained to the patients.

Adjuvant treatment is occasionally required, even if the preoperative diagnosis indicates the contrary. This does not signify that one should not perform implant-based IBR. The patients in whom this type of reconstruction is destined, must, on the contrary, be clearly informed of the risk encountered in such circumstances.[9] It is the same for women previously irradiated who have a local recurrence of their breast cancer and choose implant reconstruction. For the patients who are very likely to receive adjuvant treatments before reconstruction, it is possible to make a choice of not reconstructing with an implant immediately. Delayed reconstruction after completing the radiotherapy protocol seems to minimize the risk of complications.[10,11]

We also analyzed and compared different types of prostheses (pre-filled with saline, silicone, Becker and other expanders) used in our study population. The use of non-Becker expanders was significantly associated with implant removal. Similar results have been reported by other authors previously.[12] One may therefore suggest that these expanders have been used for poor indications of implant-based reconstruction (breast with excessive volume, irradiated tissues) and we have progressively abandoned the use of these expanders.

A link between synchronous axillary clearance and later implant removal has been suggested in the literature.[2] Neither harvest nor the number of nodes appeared to be related to implant removal in our series. Among our study group, obesity defined by the BMI was not associated with a higher risk of implant removal. However, McCarthy *et al.* reported that obesity could increase the risk of both complications and implant failure.[3]

In our series, 29 prostheses were removed either for infection, extrusion, or a combination of the two; 17 of them occurred in the first 3 months after surgery. One may therefore consider that these events have occurred early in the life of a prosthesis. All patients underwent surgical management of their complications. When a simple healing delay was the cause (4 cases), in the absence of the signs of associated infection, the implant pocket was cleaned and a new prosthesis was inserted with a drain. Some recommend dual drainage to allow postoperative saline irrigation.[7] We have no experience in this regard, but were able to preserve the implant reconstruction in the absence of signs of infection (n = 7). Three other patients in whom reconstruction could be preserved had a 'conversion', either by autologous latissimus dorsi alone or in combination with a prosthesis. Such management was considered to be adapted for the cases in whom skin necrosis with signs of infectious was the cause. Any secondary tissue defect necessitated importing 'fresh' tissue. In 7 patients with implant removal, delayed reconstruction was selected, particularly for those with infection. Then, according to the state of the thoracic tissues and wounds/scars, some could have preservation of their reconstruction by the prosthesis alone whereas others required a flap.[5]

In conclusion, this retrospective study of 738 patients undergoing IBR by retro-pectoral prosthesis allowed us to study the risk factors for prosthesis removal either due to infection or extrusion. There were three factors that proved to be statistically significant: 1) postoperative radiotherapy, 2) postoperative chemotherapy, and 3) non-Becker type expanders.

Of the 3.9% of our patients that required removal of an implant, reconstruction was ultimately possible in 75.9%. Salvage was equally distributed between immediate and delayed and musculocutaneous flaps were a precious resource. However, for a quarter of the patients, this episode was sufficient and they had no desire to pursue further reconstruction.

Conflicts of interest

None

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