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One-step breast reconstruction with polyurethane-covered implants after skin-sparing mastectomy

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KEYWORDS
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Summary *Background and aim:* Skin-sparing mastectomy (SSM) and immediate one-step breast reconstruction with implants has become an increasingly popular, effective treatment for selected patients with breast carcinoma. However, it is associated with high complication rates. Breast augmentation with polyurethane-covered implants (PCIs) has consistently had optimal short-term and long-term results with low rates of capsular contracture. The aim of this study was to evaluate the clinical and aesthetic outcomes of immediate one-step breast reconstruction with PCI after SSM in early breast cancer patients at a single institution.
Methods: We reviewed the records of 221 consecutive breast cancer patients who underwent one-stage immediate reconstruction with PCI after SSM from 1995 through 2005. Patient and tumour characteristics, type of reconstruction, postoperative complications, aesthetic results and recurrence rate were analysed.
Results: The mean age of the patients was 52 ± 11 years (range, 30—76; standard deviation (SD), 11). The American Joint Committee on Cancer (AJCC) pathologic stages were 0 (10%), I (63.3%) and II (26.7%). Thirty-nine (17.65%; confidence interval (CI) = 13.04—23.1) of the 221 patients had complications; seven had prosthesis extrusion requiring an implant (five due to skin necrosis, one due to infection and one due to late haematoma). In six of these seven cases, the procedure was indicated for local recurrence after conservative breast surgery with adjunctive radiation therapy (rescue procedure). Thirty-two (14.4%) patients had minor complications: 12 had cutaneous rash, four had malpositioned implants and 16 had inadequate implant projection. At long-term follow-up, four (1.8%) patients had developed grade IV capsular contracture associated with postoperative radiation therapy. At a median follow-up of 98 months (range, 36—156), 14 (6.3%) patients had tumour recurrence and 12.2% had distant metastasis. Nineteen patients had died of cancer, and 192 (86.8%) remained disease free.

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Conclusion: One-stage immediate breast reconstruction with PCI after SSM appears to be oncologically safe and provides a high level of patient satisfaction.

Skin-sparing mastectomy (SSM) combined with immediate (one-step) breast reconstruction can be advocated for both prophylactic and therapeutic treatments of early breast cancer.[1,2] SSM minimises deformity and allows for immediate one-step breast reconstruction with implants in women with medium-sized breasts, leading to optimal short-term aesthetic results.[3,4] Additionally, one-step SSM confers significant psychological benefit on patients and is usually favoured by working women.[5,6] However, as in other breast surgical reconstruction techniques with breast implants, the need for radiotherapy affects capsular contracture rates after SSM.[7]

In the past, polyurethane-covered implants (PCIs) were believed to carry an excessive risk of breast cancer. However, these early speculations have been disproved by a growing body of evidence, including reports of low rates of capsular contracture and an acceptable safety profile for breast PCIs.[8,9] To minimise late capsular contracture, our group systematically performed one-step immediate reconstruction with PCI after SSM in women with early-stage breast cancer or multifocal lesions, from 1995 through 2005. The purpose of the present study is to report the postoperative complications, patient satisfaction, long-term surgical outcomes and oncological safety for this surgery.

Methods

From 1 January 1995 through 31 December 2005, 221 women underwent SSM and immediate breast reconstruction with subpectoral prosthetic implantation. Surgical inclusion criteria were as follows: (1) tumour stage 0—II and (2) body mass index (BMI) < 29 kg m^{-2}. Patients were excluded if they were heavy smokers ($\geq$10 cigarettes per day), and light smokers were encouraged to quit at least 3 weeks prior to the procedure. The mean age was 52 $\pm$ 11 years (range, 30—76; standard deviation (SD), 11) and the mean BMI was 26 $\pm$ 8 kg m^{-2}. Mean follow-up time, defined as the mean interval between the operation and most recent follow-up evaluation, was 98 months (range, 36—156). Table 1 details tumour characteristics and staging, based on the American Joint Committee on Cancer staging system.

In 199 women, the procedure was intentionally curative, whereas the remaining 22 procedures were prophylactic. One-stage SSM was performed unilaterally in 198 patients and bilaterally in 23 patients. Seventeen of the 23 bilateral procedures were curative mastectomies coupled with contralateral prophylactic mastectomies; the remaining six were bilateral prophylactic mastectomies. Out of 221 patients, 80 (36.2%) underwent postoperative radiation therapy because of more than three positive lymph nodes or tumour in close proximity to the skin.

Surgical technique

All women underwent the standardised technique reported previously. Mastectomy included resection of the nipple—areola complex. For cosmetic reasons, the incision was extended in most patients caudally or laterally. Care was taken to resect all mammary glandular tissue, preserving the inframammary fold ligament. In 197 patients, an axillary lymph node dissection was performed en bloc with the mastectomy in accordance with the preoperative plan; in 24 patients, mastectomy was combined with a sentinel lymph node procedure. Immediately following the SSM, a partial subpectoral pocket was created to allow implantation of a Silimed anatomical silicone gel-filled PCI (Silimed, Rio Janeiro, Brazil). In order to prevent cranial displacement of the implants and to allow for a more naturally projecting lower part of the reconstructed breast, inferior detachment of the pectoralis major was performed (dual plane technique). The average volume of the implant was 355 cc (range, 165—495). The caudal edge of the pectoralis major muscle was subsequently sutured to the subcutaneous tissue of the caudal skin flap. Antibiotic prophylaxis and two drainages, in the implant pocket and axilla, were routinely applied in all patients. The cosmetic result was assessed prior to skin closure by placing the patient in a semi-sitting position, with the arms brought close to the trunk. Late (after 6—12 months) nipple—areola complex reconstruction was performed with a star flap and tattoo in 60% of cases.

Patient satisfaction and quality of life

Patient satisfaction was assessed based on patients' perceptions of several aesthetic aspects while dressed and undressed: (1) general satisfaction and (2) breast characteristics (shape, size, texture and symmetry). We used a

Table 1 Tumour characteristics.

Characteristic	Frequency (%)
Tumour histology	
Ductal carcinoma	57
Lobular carcinoma	23
Other invasive type	20
Tumour stage	
T0	10
T1	63.3
T2	26.7
Node stage	
N0	33.3
N1	66.6

Likert scale: 5, excellent; 4, very good; 3, good; 2, fair; and 1, bad.

The 36-Item Short-Form Health Survey (SF-36) questionnaire, the well-known, validated questionnaire for quality-of-life assessment, was administered 3 months after surgery.[10,11] This questionnaire evaluates health status with two separate components: mental health and physical health. The physical health component includes four scales comprising 10 questions about physical functioning (PF), four questions about role limitation due to physical problems (RP), two questions about body pain (BP) and five questions about general health (GH). The mental health component also includes four scales. These comprise four questions about vitality (VT), two questions about social functioning (SF), three questions about role limitation due to emotional problems (RE), five questions about mental health (MH) and one question about general health perception. Each of these eight subscales is scored separately, from 0 to 100. A higher score in each subscale indicates a better condition.

Statistical analysis

Continuous variables are described as mean ± standard deviation (SD) or medians with range. Statistical analysis was conducted with Openepi (United States Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA, USA) to calculate 95% confidence intervals (CIs).

Results

In 39 (17.6%; CI = 13.04—23.1) patients, one or more postoperative complications occurred. Prosthesis extrusion requiring implant removal occurred in seven patients (due to skin necrosis in five, infection in one and late haematoma in one). In six of these, the procedure for local recurrence after conservative breast surgery with adjunctive radiation therapy (rescue procedure) was indicated. As many as 32 patients had minor complications: 12 had a cutaneous rash, four had malpositioned implants and 16 had inadequate implant projection. At long-term follow-up, grade I—III contracture had not occurred, but four patients developed grade IV capsular contracture. All contractures were associated with postoperative radiation therapy. Fourteen (6.3%) patients had tumour recurrence and 27 (12.2%) had distant metastasis. Nineteen patients died of cancer and 192 (86.9%) remained disease free.

Quality of life was optimal at 3 months after surgery (Table 2). General patient satisfaction while dressed was either 'very good' or 'excellent' in 100% of cases. Patient satisfaction while undressed was either 'good' or 'very good' in 93.3% (Figures 1 and 2). Regarding specific breast features, patients frequently reported excellent or very good results with regard to shape (100%), size (100%), texture (86.7%) and symmetry (100%).

Table 2 Patient satisfaction scores for the SF-36 questionnaire ($N = 221$).

Subscale	Median	Range
Physical Health		
Physical functioning	84	82—87
Body pain	78	76—81
Role limitation due to physical problems	77.5	73—82
General health	74	71—76
Mental Health		
Social Functioning	85.5	83—88
Role limitation due to emotional problems	77	72—80
Mental health	74	70—78
Vitality	60	57—63

Discussion

In this study, one-stage SSM and immediate prosthetic reconstruction with PCI were associated with high patient satisfaction, a low complication rate, a low rate of capsular contracture and an optimal long-term outcome. The re-operation rate was 3.2%, and severe capsular contracture (Baker 3) was found in <2% of the cases. These results are especially encouraging given the extended follow-up period (median, 8 years) and the fact that almost a quarter of the patients underwent post-mastectomy radiation therapy. Several studies have indicated that radiation therapy can adversely affect aesthetic outcomes after implant reconstruction following SSM. Of note, the most severe complications in the present study (six out of seven) occurred in the context of SSM after a previous conservative surgery and radiotherapy.

Although SSM with delayed breast reconstruction may allow an optimal aesthetic outcome with efficient delivery of radiation, a safe, single-stage SSM procedure offers a significant emotional advantage to the patient.

Our short-term results contrast with prior SSM studies using silicone implants. In a recently published Dutch study, 215 females who underwent SSM reconstruction had a 29% complication rate and a 14.4% re-operation rate.[12] Kobraei et al. reported a 32% overall in-hospital complication rate and a 14% re-operation rate for 102 patients.[3] Regular silicone or saline implants were used in both of these studies. Although differences in study population and design may explain the diverging results of these studies and our own, our choice of PCIs is likely a contributor. There is a wealth of evidence favouring the use of silicone gel-filled PCIs for breast augmentation, including low rates of complications and contracture.[13]

Immediate one-stage breast reconstruction with implants is best indicated in patients who desire minimal or no change in breast volume and have small or medium round breasts (200—400 g) with minimal ptosis. Concomitant presence of severe ptosis or hypertrophy of the contralateral breast usually calls for reduction or mastopexy to achieve symmetry. Immediate breast reconstruction requires meticulous planning, accurate marking and accurate implant selection during surgery using sizers and the weight of the resected gland. The location of the new inframammary fold (reconstructed breast) is essential for an optimal aesthetic result and should be symmetrical with the contralateral one if no ptosis is present. In the case of

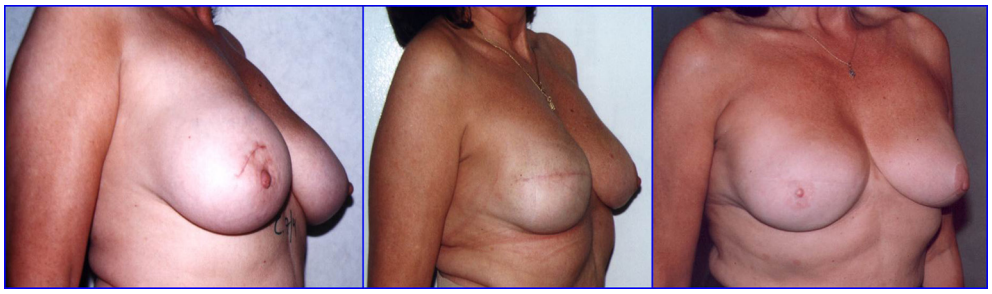

Figure 1 Left: Preoperative photographic image. Note right breast with biopsy scar. Center: Six months after skin-sparing mastectomy with immediate reconstruction using an anatomic 395 g polyurethane-covered implant. Right: Six years after surgery. Nipple-areola complex reconstruction was performed 8 months after index surgery.

contralateral ptosis, the new inframammary fold should be placed 2 cm lower, probably resulting in asymmetry of the inframammary folds but visually appropriate.

Implant selection remains a key element with this technique. It is best for the operator to match the implant base and height with the breast measurements. This is done simply, with a calliper and a measuring tape. Because anatomical silicone implants are made of highly cohesive gel, they are usually selected to be 1 cm smaller than the breast base and height. Implant projection is also selected according to the contralateral breast. In most scenarios, maximum projection is chosen to achieve symmetry.

PCIs resulted in acceptable rates of local recurrence (6.3%), similar to rates reported for silicone implants. Newman et al. reported 6.2% local recurrence in 372 patients with T1/T2 tumours,[14] whereas the group from Emory University reported a rate of 5.5%.[15]

PCIs are currently available in more than 60 countries, including several European countries (i.e., Belgium, Germany, Italy and Portugal), Russia and all of Latin America. At this moment, a Food and Drug Administration (FDA) register is still lacking. In March 1989, an unpublished study showed that polyurethane foam, a material used for coating on certain types of silicone gel-filled breast implants, would degrade and release 2-toluene diamine. This chemical compound has shown to increase cancer risk in animal models (under conditions of high temperature and alkalinity). The FDA requested specific information from the PCI Company regarding the chemical process of manufacture along with safety testing of polyurethane foam. Shortly afterwards, the company removed PCI from the US market voluntarily. In July 1991, an FDA Panel reviewed the risk of polyurethane foam coating and stated that the risk was small and it did not advise surgical removal of already implanted prosthesis.[16]

Regardless of the surgical technique and breast prosthesis, the loco-regional recurrence rate after total mastectomy has remained constant over the years. Local recurrence is probably explained by the complex interplay of tumour size and stage at the time of excision and nodal involvement. As expected, recurrence is more rapid for more advanced tumours. The median time to local disease was 3 years, depending on tumour stage. Thus, our extended follow-up period allowed us to detect the most

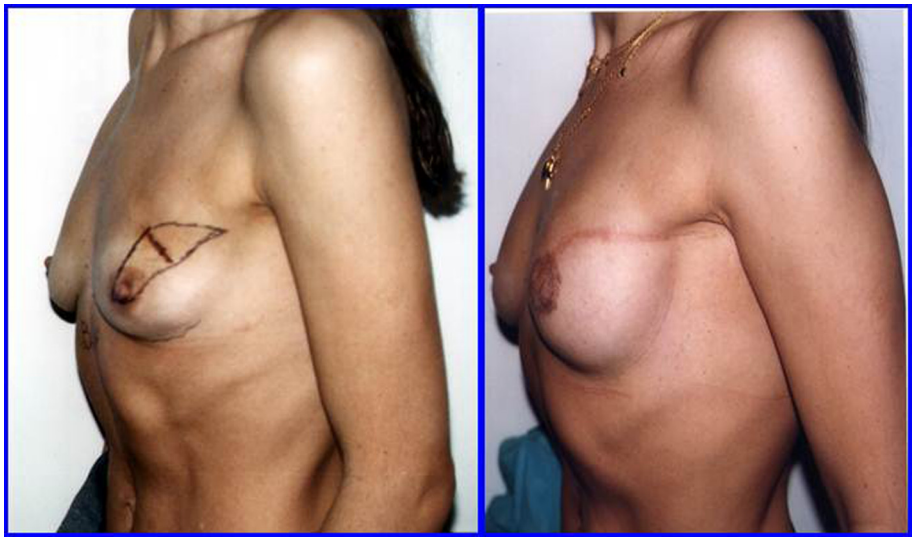

Figure 2 Left: Preoperative image showing the left breast of a young female with a multicentric lesion. Right: Five years after skin-sparing mastectomy and immediate reconstruction with an anatomic 215 g polyurethane-covered implant and subsequent nipple—areola complex reconstruction.

clinically relevant local and distant recurrences. Typically, local recurrences were observed either in the skin or in the subcutaneous tissue of the chest wall. Achieving a low rate of local recurrence is critical, since disseminated disease almost invariably follows local recurrence after total mastectomy. Thus, local recurrence is rarely an isolated event due solely to insufficient surgical excision; rather, it is a component of widespread relapse.

Limitations

This was a retrospective, observational study with a small sample. However, it constitutes the first series of patients undergoing SSM with immediate one-step breast reconstruction using PCI and who were followed up for an extended period of time (median, 8 years).

Conclusion

One-stage breast reconstruction with a PCI immediately after SSM appears to be safe and provides a high level of patient satisfaction.[13] The polyurethane adhesive resists rotation, a common problem with anatomical implants. It also prevents excessive friction between the implant and the surrounding tissue, thereby resisting haematoma and seroma formation.[8,9] In carefully selected cases, this modality of breast reconstruction is a good option, offering rapid convalescence and lower cost.

Disclosure

The authors have no commercial interest in any of the materials cited in this article.

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