



The surgical and oncological safety of immediate breast reconstruction

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Summary Aim. The aim of our study was to (1) examine the incidence of surgical complications, (2) determine the incidence of loco-regional recurrences and (3) examine the safety of saving the nipple-areola-complex after immediate breast reconstructions in breast cancer.

Methods. Sixty-six immediate breast reconstructions were performed. Wide local excision (WLE), skin sparing mastectomy and subcutaneous mastectomy (SCM) were performed to 12, 20 and 34 patients, respectively. In all patients with WLE the reconstruction was performed with the latissimus dorsi (LD) miniflap. In other patients reconstructions were done with a free TRAM-flap ($n = 26$), LD-flap ($n = 27$) or with a prosthesis only ($n = 1$).

Results. Major flap necrosis developed in four patients. Local recurrence rate was 8.3% in the group where nipple-areola-complex was removed and 7.1% in the group where nipple-areola-complex was saved. Metastases were found in 12.5 and 0%, respectively.

Conclusion. SCM compared to skin sparing mastectomy may lead to an enhanced risk of immediate surgical complications, but does not threaten the oncological safety. Saving the nipple-areola-complex in immediate breast reconstructions is possible in early breast cancer, if the tumour is not in the central part of the breast.

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Introduction

Immediate breast reconstruction after skin-sparing mastectomy (SSM) improves cosmesis through preservation of the skin envelope of the breast. It is an oncologically safe approach for the management of

patients with early breast cancer.¹⁻³ Also, subcutaneous mastectomy (SCM) combined with breast reconstruction with either a free TRAM-flap or a latissimus dorsi (LD) musculocutaneous flap or wide local excision (WLE) and LD-miniflap has the same goal: minimizing the deformity of the breast without compromising radicality.⁴ Surgical complications after SSM or SCM include skin necrosis leading to infections and additional operations.^{5,6} Flap reconstructions may have a high incidence of

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surgical complications, e.g. seromas in flap donor sites and partial or total flap losses.⁷⁻⁹ Chest wall skin is a common site of local recurrence (LR) after mastectomy with a reported incidence after SSM of 2-7%.^{1,10}

The aims of this study were to examine firstly the incidence of surgical complications, secondly the incidence of loco-regional recurrences during a first 3-year-period, and thirdly the safety of sparing the nipple-areola-complex. The series presents the first 66 patients of our unit to whom immediate breast reconstructions were performed not only in ductal carcinoma in situ (DCIS) but also in invasive breast cancer.

Patients and methods

Patients

This study was approved by the ethics committee of Kuopio University Hospital. From January 1998 to June 2001, 66 patients with primary breast cancer underwent an immediate breast reconstruction following SSM, SCM or WLE in our unit. Before 1998 immediate reconstructions were rarely performed. Most reconstructed patients then had DCIS. The patients presented here are the first patients undergoing immediate reconstructions with more liberal indications. All patients were examined preoperatively with triple assessment: clinical examination, mammography + ultrasound examination and core biopsy. No routine MRI was used. All patients had preoperative cancer diagnosis by image-guided core needle biopsy. The method of operation was planned in a multidisciplinary team by using the available preoperative clinical, radiological and histological data. Neo-adjuvant chemotherapy was not used in patients undergoing immediate breast reconstruction. Data was reviewed for surgical complications and post-operative oncologic treatments in early 2003. The oncological data was re-examined in December 2003.

Operative procedures and pathologic examination

Tumours were treated by WLE and LD-miniflap, SSM or SCM followed by a large musculocutaneous LD-flap or a free TRAM-flap. SCM (nipple-areola-complex saving subcutaneous mastectomy) was used instead of SSM (the nipple-areola-complex and the skin above the tumour excised) if the tumour was located further than 3 cm from the

areolar region. In all patients with SCM, the areola was undermined as thin as a full thickness skin graft, and a perioperative frozen section examination from the subareolar space was performed. The final pathologic result of this tissue was carefully checked also post-operatively. If there was evidence of cancer cells in the subareolar space, the nipple-areola-complex was later removed. The preoperative biopsy tract was usually excised during the operation. Before year 2000, axillary lymph nodes were examined with axillary clearance, but in DCIS only sampling of lymph nodes was performed. After that, patients with DCIS or tumours under 2 cm undergoing immediate breast reconstruction had sentinel lymph node biopsy including perioperative frozen section examination. Axillary clearance was performed, if sentinel node biopsy revealed metastases.

In reconstructions following SCM and SSM the flap selection was performed depending on the size of the opposite breast, the age and body status of the patient and according to the diseases and earlier operations of the patient. Patients with TRAM-flaps were followed in the post-operative care unit until the next morning. In subcutaneous mastectomies, where the flap is buried, a thermometer was used inside the TRAM-flap to show whether there were problems with the perfusion of the flap. In buried LD-flaps only indirect methods were used to follow the perfusion of the flap. Unusual bleeding into the drains or oedema of the reconstructed breast were indications for reoperation.

Oncological treatment

All patients with WLE were given post-operative radiotherapy (RT) to the breast. RT included CT-based dose planning and fractionation to 2.0 Gy per day, 5 days per week up to a total dose of 50.0 Gy. In case of SSM or SCM, the need for RT was evaluated by a multidisciplinary team after the final pathologic results from both the tumour and the axillary nodes. In axillary node positive cases (if there was a metastases in one or more nodes, but not if there was only micrometastases) the RT fields included also the axilla and the supraclavicular region. Also, the need for adjuvant chemotherapy and/or hormonal treatment were planned according to the national guidelines.

Follow-up

The patients were followed-up according to the local guidelines of breast cancer treatment which have been derived from the national guidelines. During the first 2 years, the patients were followed

by an oncologist or a surgeon, and thereafter once a year by their own doctors, usually general practitioners. A mammography was taken 1 year after the operation, and every second year thereafter. The ultrasound or MRI was taken when clinically needed. If recurrence was suspected, a core or open biopsy was scheduled in our hospital to verify regional recurrences (RR) or LRs.

Results

Material

The data of all patients are presented in Table 1. The nipple-areola-complex was removed in four of the 12 WLE. In Table 2 patients are presented in the groups according to the method of mastectomy and in Table 3 in the groups according to the method of reconstruction.

Immediate surgical complications

In the free TRAM-flap group three patients suffered from major flap necrosis and the flaps were removed. In one patient a re-operation was needed

for the suspicion of an anastomosis problem. One LD-miniflap was lost due to perioperative arterial damage of the pedicle. Seroma of the back (leading to aspirations) during hospital stay or during the first post-operative month occurred in 25% of patients with LD-miniflap and in 62% of patients after conventional LD-flap. Three patients with TRAM-flaps had seromas in the axillary region. In the SCM group skin and partial areola necrosis together occurred in 17.7% of patients, but were most often treated with conservative methods. One skin necrosis leading to conservative treatment occurred in the flap donor site of a LD patient. Two nipple-areola-complexes were lost due to necrosis. In one case, cancer cells were found in final pathologic examination taken from the subareolar space, which was another reason to remove the nipple-areola-complex. Other surgical complications remained few.

Surgical complications after one month

One patient with WLE + LD-miniflap had an infection of the seroma, and also septicaemia and cellulitis of the breast. One patient with SCM + TRAM-flap had an erysipelas-type of infection of the breast, which was followed by lymphoedema of the breast lasting for 1 year. A persisting fistula leading to infections in a patient with SCM and TRAM-flap was later treated by removing the nipple-areola-complex. All patients who lost their nipple-areola-complex are analysed in the group where they belonged at the beginning of the study. All other patients with nipple-areola saving reconstruction have announced to have some (but not normal) sensation in the areolar region, but no prospective touch sensibility tests have been made. Two patients with TRAM-flaps and post-operative RT developed hardness and asymmetry of the middle part of the breast.

Oncological viewpoints on complications

In Table 4 patients are presented in the groups according to the method of nipple-areola-complex removal. Surgical complications (skin necrosis) delayed the oncological treatment in only one patient (starting after 7 weeks from the operation). In six patients the reason for a delayed start of oncological treatment (from 7 to 10 weeks) was due to the capacity of the RT unit to start the treatment. One patient with RR in one axillary lymph node and two patients with subcutaneous LR were treated surgically and with chemotherapy. One patient with LR and suspicion of metastases in lymph nodes of both axillary regions was on

Table 1 Tumour characteristics

Tumour classification	<i>n</i>
DCIS	12
T1	33
T2	16
T3	4
Nodal status	
N0	47
N1	18
Grading of the tumours	
G1	17
G2	25
G3	9
Not known ^a	14
Hormone receptor status	
Oestrogen positive	46
Oestrogen negative	5
Not known ^a	15
Progesterone positive	44
Progesterone negative	7
Not known ^a	15
Multifocal/-centric	
Yes	20
M No	45

DCIS, ductal carcinoma in situ.

^a Not known includes 12 DCIS, 1 tumour malignum phylloides, 1 tumour not found in the breast (reason for the operation = axillary metastasis and earlier cancer of the other breast, also not included in tumour classification).

Table 2 Data according to mastectomy method

	WLEX + LDMF	SSM + TRAM/or LD	SCM + TRAM/or LD/or prosthesis
N	12	20	34
Age	55.3 ± 3.6*	46.5 ± 2.8**	47.5 ± 2.7***
Tumour classification			
DCIS	1		11
T1	6	8	19
T2	5	8	3
T3		4	
NAC spared	8		34
NAC excised	4	20	
Oncologic treatments			
Radiation therapy	12	11	13
Chemotherapy	5	11	11
Immediate complications			
Seroma	3	10	16
Skin necrosis		1	4
Areola necrosis			2
Flap necrosis	1	2	1
Delayed complications			
Hernia of the abdomen		1	1
Contracture of the prosthesis			1
Fistula under the mamilla			1
Re-operation for nerve damage			1
Late infection	1		1
Local recurrences		2	3
Regional recurrences			1
Multiple metastases		3	

WLEX + LDMF, wide local excision + latissimus dorsi mini flap; SCM, subcutaneous mastectomy; SSM, skin sparing mastectomy; TRAM, transversus rectus abdominis muscle flap; LD, latissimus dorsi musculocutaneous flap; NAC, nipple-areola-complex. * $p < 0.01$ (WLEX + LDMF vs SSM + TRAM/or LD, *T*-test). ** $p > = ns$ (SSM + TRAM/or LD vs SCM + TRAM/or LD, *T*-test). *** $p < 0.01$ (SCM + TRAM/or LD vs WLEX + LDMF, *T*-test).

hormonal treatment first and later on chemotherapy. One patient with SCM and TRAM-flap for DCIS had LR in two subcutaneous lymph nodes after 5 years from primary operation. A part of the flap was removed with later RT and chemotherapy. All other recurrences appeared within 2 years from primary

operation. Three patients died of metastatic disease. Their age at the moment of operation was 38, 40 and 45 years. The TN-classification of these three patients was T3N2, T3N0 and T2N1, respectively. Age 40 years or younger (local or diffuse metastases in 45.5% of patients 40 years or

Table 3 Surgical complications according to the flap

	WLEX + LDMF	SSM/or SCM + TRAM	SSM/or SCM + LD
<i>n</i>	12	26	27
Immediate complications			
Seroma	3	3	16*
Skin necrosis		3	2
Areola necrosis		1	1
Flap necrosis	1	3	
Delayed complications			
Hernia of the abdomen		2	
Fistula under the mamilla		1	
Reoperation for nerve damage			1
Late infection	1	1	

One patient with prosthetic reconstruction not included in the groups. * $p = ns$ (SSM/or SCM + LD vs WLEX + LDMF, Fisher's *t* exact test).

Table 4 Data of the comparison between Groups 1 and 2

	Group1 nipple-areola removed	Group 2 nipple-areola spared
<i>n</i>	24	42
LR	2	3
RR	0	1
Multiple metastases	3	0
Follow-up time (years)	3.7 ± 0.7	3.8 ± 1.1, <i>p</i> = ns*
DCIS or tumour size T1	37.50%	85.40%, <i>p</i> < 0.01**

LR, local recurrence; RR, regional recurrence; DCIS, ductal carcinoma in situ. Group 1, skin sparing mastectomy and wide local excision containing nipple-areola-complex removal. Group 2, subcutaneous mastectomy and wide local excision sparing nipple-areola-complex. *T-test; **Fisher's *t* exact test.

younger vs in 7.3% of patients over 40 years of age, *p* < 0.01) and large size of the tumour are risk factors to recurrences in our material.

Discussion

By some authors the free TRAM-flap is the method of choice in immediate breast reconstructions,¹¹ but also prostheses are commonly used.¹² The cosmetic result of the reconstruction with implant and post-operative RT is not always satisfactory.¹³ Patients with TRAM-flaps have greater general and aesthetic satisfaction compared to implant patients.¹⁴ In our material, most immediate reconstructions in the first years of the study period were performed with free TRAM-flaps, but nowadays the LD musculocutaneous flaps are more often used. Also, WLE with LD-miniflaps have become more popular in recent years.

Partial or total flap loss is a serious complication in any reconstructive surgery. In a study concerning the complications of microvascular surgery, the incidence of total flap loss was 4.1% and the incidence of early thrombosis of the vessels 9.9%.¹⁵ In our material, during 1998 we lost two free TRAM flaps. The learning curve in microvascular surgery is a well-known reason for flap complications: in the article of Nieminen et al. from their 175 patients with free TRAM flaps (27 immediate and others delayed) two flaps were lost and additional eight patients were reoperated for thrombosis of the vessels. The surgical complication rate was nearly 50% in first 50 patients but decreased to 20-25% in later patients.¹¹ Not only the technique of the microvascular anastomoses but also the post-operative monitoring of free flaps during the first days requires experience. With SCM the flap is buried. In the article of Disa et al. the flap loss rate was significantly higher in buried flaps compared to non-buried flaps. Only non-buried flaps could be saved in their material.¹⁶ In 1998,

we had only a thermometer in the flap and clinical observation to show whether the perfusion of the flap was good or not. Nowadays, we use the microdialysis technique in free flaps during the first 2 days. There is also other known methods to find the problems of the vessels after microvascular anastomosis, e.g. the indocyanide technique.¹⁷ During the later years in this material, we lost one free TRAM-flap and one LD-flap. Total loss of LD-flaps are rare also according to literature, incidence ranging from 0 to 1%.^{3,7}

Skin necrosis after SSM or SCM may lead to a delay in the oncological adjuvant treatments.^{3,4} When removing the tumour, the surgeon has to be careful not to make the skin envelope too thin thus increasing the risk of skin necrosis. On the other hand, residual breast tissue under the skin leads to an enhanced risk of a LR. Oncological safety of the skin sparing techniques is discussed in only few articles, in which the follow-up time reaches 6 years.^{1,2} In this material, the follow-up time is still rather short (mean 3.8 years, range 2.4-5.8 years). However, in invasive breast cancer 75% of LRs are usually seen during the first 3 years.¹ In our material all except one of the recurrences appeared within 2 years from the operation. The incidence of LRs after immediate reconstructions may be compared to LRs after breast conserving therapy. In a material of Clough et al. the breast conserving cancer operations were performed with reductionplasty techniques followed by RT. The incidence of 5-year LRs was 9.4%.¹⁸ In the report by Spiegel et al., with a follow-up time after SSM with immediate reconstructions of at least 6 years, the incidence of LR for invasive cancer was 5.5% and for DCIS 0%.² We observed LR in two lymph nodes under the skin envelope (after SCM) in one patient with DCIS after 5 years. Residual breast tissue was seen farther from that area in a resected part of the breast in a reoperation. Although the LRs are usually in the remaining breast skin and easy to find, most relapses are invasive cancers. In the article of Langstein et al., they concluded that subcutaneous

recurrence in the skin envelope of the breast has usually a better prognosis than recurrence in the chest wall.¹⁰ In one of our young patients with LR in the chest wall skin 2 years after the primary operation a very large area of DCIS was found in her breast and invasive component was located in the medial upper quadrant of the breast in the primary operation. Healthy margins around the tumour were very small, especially towards the pectoralis major fascia (only a very thin breast tissue is also usually seen in that area of the breast). One reason for an LD-flap in her case was that the wound could not have been closed without the flap. Therefore, her operation was not really a SSM, because all of the skin in the medial part of the breast was removed to achieve radicality.

In invasive cancers, most LRs appear during the first 3 years.¹ Advanced disease is the most significant prognostic factor for LR.¹ In a study by the EORTC group (van Dongen et al.) in T2 tumours loco-regional recurrences were more frequent in patients treated with conservative surgery compared to patients treated with mastectomy (20% vs 12%, respectively, $p = 0.01$).¹⁹ In our material, patients with larger tumour size had more LRs, RRs and metastases (6.7% of patients with DCIS and invasive T1 tumours compared to 30% of the patients with T2 or larger tumours, $p = 0.02$). This does not support the findings by Kroll et al. who found that the tumour size did not affect the risk of LRs or metastases.²⁰ It is likely, that three of our patients (with advanced disease and young age) who succumbed to metastatic relapse would have died because of their cancer even if their surgery had been plain radical mastectomy and axillary clearance. The surgical technique, when radical with respect to cancer and allowing oncologic adjuvant treatment in due time, has little prognostic significance.

In our patient with RR the recurrence came so soon that it is possible that the node was not removed in the first operation. Now, we use the sentinel node biopsy in all patients with tumours under 3 cm and also in DCIS because microinvasive cancers are often seen, despite the first diagnosis of the tumour in core biopsy being pure DCIS. Late axillary clearance in a secondary operation is more difficult than doing it primarily and it may also compromise the safety of the flap. If micrometastases are found in the final histological examination of the sentinel node, it is not clear whether the axilla should be evacuated in another operation or only gives RT. In our unit no reoperation is made if immunohistochemical staining reveals only micrometastases. RT is given to the axillary area only to

patients who have a high risk of recurrence according other prognostic indicators.

The periareolar incision provides good cosmesis in breast reconstructions without reducing the range of options.²¹⁻²⁵ The distance between the tumour and the nipple-areola-complex should be at least 4 cm, and the tumour should be small according to Cense et al., if the areola is spared.²⁶ In our material, we took a sample for frozen section from the subareolar space from all patients with SCM, and the areola was prepared as thin as a skin graft. This leads often to small areas of local necrosis in the nipple and areolar region. However, most of these heal conservatively in a few weeks. On the other hand, if the necrotic are is larger, the surgeon has to perform an immediate new operation, because the delay in the oncological treatment is not justified. In this material during a median follow-up time of 3.6 years we did not find this technique to lead to a higher risk of LR (Table 4). Patients with nipple-areola-complex sparing WLE or SCM had more DCIS or smaller invasive tumours compared to patients whose nipple-areola-complex was removed (Table 4).

In this material, no prospective skin touch tests were performed, but the patients had some sensation in the nipple-areolar-complex. In the article of Benediktsson et al. touch sensibility was substantially retained after SCM and immediate reconstruction.²⁷ The benefit of SCM is mostly cosmetic. After TRAM-flaps with post-operative RT loss of symmetry and need for additional flaps to correct flap contracture have been found in more than half of the patients.²⁸ Also in our material, two patients with TRAM-flaps and post-operative RT had later hardness and asymmetry of the reconstructed breast indicating liponecrosis.

Conclusion

The preoperative use of a multidisciplinary team is recommended in order to achieve an oncologically and surgically appropriate treatment for breast cancer patients. In immediate reconstructions the patient has to understand the risks related to different treatments methods, especially to immediate surgical complications. The patients with locally advanced disease related to poor prognosis are not usually treated with immediate reconstructive methods for economical reasons. With appropriate patient selection new oncoplastic methods are usually surgically and oncologically safe.

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