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Complications following subcutaneous mastectomy with Immediate Breast Reconstruction

A retrospective observational study conducted at the Department of Urology, Breast and Endocrine- and Plastic and Reconstructive Surgery, UNN Tromsø

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Master's thesis in Medicine MED-3950 June 2022

1 Preface

A master thesis published in 2017 reported that 56% of the breasts operated with subcutaneous mastectomy with immediate breast reconstruction at the University Hospital of North Norway (UNN) Tromsø developed one or more postoperative complications (1). Based on the complication rate and new research on the field, changes were made to the surgical technique at UNN Tromsø. This thesis investigates whether these changes, including the implementation of vertical incision, hydrodissection and prepectoral breast reconstruction, has led to a reduction in postoperative complications following this type of breast surgery.

Throughout my medical studies, I have had a growing interest for Woman's health and surgery. In the autumn of 2020, I was therefore put in contact with my main supervisor Marit Helene Hansen who is chief physician at the Section for Breast and Endocrine Surgery at UNN Tromsø. Data was collected retrospective from the electronic medical records of all the patients who underwent subcutaneous mastectomy with immediate reconstruction during 2017-2021. Further, statistical analyzes of the data were performed. All the collection of data and statistical analyzes were done by me. The study was approved as a quality assurance study by the data protection officer at UNN Tromsø and no funding was received. Working with this master's thesis has been exciting, rewarding and very educational.

A special thanks goes to my inspirational supervisors, Marit Helene Hansen, and co-supervisor Solveig Nergård. Thank you for sharing your knowledge in this interesting topic and for letting me scrub in on operations. Thank you for reading through my thesis and for giving me helpful advice throughout the process. To my family and Hans Erik, thank you for your love, support and for always being there for me.

Tromsø, 31.05.22

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2 Abstract

Background

Breast cancer is the most frequent cancer among Norwegian women, and one of the surgical treatments involves subcutaneous mastectomy with immediate breast reconstruction. A master thesis published in 2017 reported that 56% of the breasts that underwent this type of surgery at UNN Tromsø, developed one or more postoperative complications. Based on the complication rate and new research on the field, changes were made in the surgical technique. The purpose of this study is to investigate if changes made in the surgical technique at UNN Tromsø has led to a reduction in postoperative complications. The changes include implementation of vertical incision, hydrodissection and prepectoral breast reconstruction.

Materials and method

The study was conducted as a retrospective observational study for quality assurance at the Department of Urology, Breast and Endocrine- and Plastic and Reconstructive Surgery at UNN Tromsø. All patients having undergone subcutaneous mastectomy with immediate reconstruction during 2017-2021 were included.

Results

A total of 87 patients (138 breast) were included in the study. The postoperative complication rate was reduced from 56% in the previous thesis to 32% in this study. Breasts operated without the HD technique had a significantly higher rate of skin flap necrosis ($p = 0.004$). Vertical incision was the most frequent used incision and was used in 50% of the breasts. No significant difference in complication rates were found when comparing prepectoral and subpectoral reconstruction. Reoperation was needed in 42% of the breasts because of complications and 31% of the breast needed one or more additional surgeries to obtain a cosmetic favorable result.

Conclusion

A reduction in postoperative complications was found after the changes were made in the surgical technique. Vertical incision was used most frequent, and breasts operated without the HD technique had a significantly higher rate of skin flap necrosis, indicating that HD and vertical incision may have had a contributing factor to the reduction.

3 Abbreviations and definitions

ADM: Acellular dermal matrix, biologic surgical mesh

BMI: Body mass index

BCS: Breast-conserving surgery

CI: Confidence interval

DCIS: Intraductal carcinoma

DIEP: Deep inferior epigastric perforator

DIPS: Distributed Information and Patient Data System in Hospitals

HD: Hydrodissection, tumescent dissection

IMF: Inframammary

LD: Latissimus dorsi

LICAP: Lateral intercostal artery perforator

LTAP: Lateral thoracic artery perforator

NAC: Nipple-areola-complex

NSM: Nipple-sparing-mastectomy, total sparing mastectomy

SSM: Skin-sparing-mastectomy

SPSS: Statistical Package for the Social Sciences

TIGR-matrix: Synthetic surgical mesh

TE: Tissue expander

UNN: University Hospital of North Norway

BRCA1 and BRCA2 Breast cancer gene 1 and 2. These are tumor suppressor genes that help to regulate cell division. Mutation in either of these genes increase the risk for breast cancer.

Adjuvant therapy Additional cancer treatment given after the primary treatment to lower the risk of cancer recurrence.

Postoperative Period following a surgical operation.

Mastopexy Breast lift.

4 Introduction

Breast cancer is the most frequent cancer among Norwegian women. In 2019, 3726 women got diagnosed with breast cancer, that being the highest number ever to be registered in Norway. With the implementation of the mammography screening program and improved treatments, the survival has increased and patients that can't be cured, now live longer with the disease (2).

Surgical treatment for breast cancer involves breast-conserving surgery (BCS) with or without the use of oncoplastic techniques, or mastectomy alone or with immediate or delayed breast reconstruction (3). If there are no contraindications, all patients undergoing mastectomy should be offered breast reconstruction and be educated on their options (3). The goal of the breast reconstruction is to create a breast as similar as possible to the breast before the operation, without expense of the actual breast cancer treatment (3). Immediate breast reconstruction is associated with improved quality of life (4), better self-esteem, improved psychological welfare (5), fewer complications (6), and a better cosmetic result than delayed reconstruction (7). The mastectomy technique is chosen based on the timing of the reconstruction (8), and the patients that are planned for immediate reconstruction are being operated with subcutaneous mastectomy (3).

However, no surgery is without the risk for complications. A master thesis evaluating postoperative complications in 57 patients (88 breasts) that underwent subcutaneous mastectomy with immediate reconstruction at UNN Tromsø during 2014-2016 found that 56% of the breasts developed complications, where 35% needed one or more reoperations due to the complications (1).

Complications following breast surgery may cause more suffering for the patient, a less aesthetic favorable result, increased hospital expenses, or delay additional cancer treatment (2, 9-11). Based on the findings in the thesis (1) and new research on the field, changes has been made in the surgical technique at UNN Tromsø. A new subcutaneous mastectomy technique called hydrodissection (HD) was gradually introduced in 2019. In addition, vertical incision was implemented in 2018. Changes has been made in the breast reconstruction as well. The breast implants are now, from 2017, more often being placed in the prepectoral space instead of under the pectoralis muscle. Subpectoral placement was the standard procedure before.

4.1 Subcutaneous mastectomy with immediate reconstruction

Subcutaneous mastectomy with immediate breast reconstruction is an operation that requires close cooperation between the breast surgeon and plastic surgeon (3). It's an operation that demands experience, where the choice of surgical technique, reconstructive method and additional treatment should be discussed in a multidisciplinary team including a breast surgeon, plastic surgeon, radiologist, and oncologist (3). The main goals for the surgical treatment of breast cancer are local control, improved survival and avoiding locoregional relapses (3). To remove all clinical evidence of breast cancer, the surgical techniques has evolved drastically over the past 30 years (12).

Mastectomy is indicated when breast-conserving surgery (BCS) has shown to be unsuccessful or contraindicated, when the patient does not want BCS, when radiation therapy is not feasible, and in inflammatory cancer and for gene mutation carriers (3). Women with BRCA1 or BRCA2 mutations is shown to have an increased lifetime risk for breast cancer (13), and studies shows that bilateral prophylactic mastectomy reduces the risk in these patients (14, 15). Risk reducing mastectomy is therefore offered to these women, in addition to women from families with high accumulation of breast cancer where no mutation has been found (3). At diagnosis of breast cancer there is no general indication for prophylactic removal of contralateral breast and it does not improve the prognosis (3), but the woman might have fear and anxiety about developing cancer in the healthy breast leading her to operate it (16). More genetic testing has caused prophylactic mastectomy to increase and high demands are being placed on the cosmetic result (17).

Types of mastectomies being used now includes modified radical, simple, skin-sparing or nipple-sparing (12). In modified radical mastectomy the pectoralis muscle is preserved, while the breast and axillary lymph nodes inferior, lateral and posterior to pectoralis minor is removed (12). Simple mastectomy removes the breast including the nipple and areola with a large ellipse of the skin (12). Subcutaneous mastectomy can be done with or without excision of the areola based on factors such as tumor size, distance from tumor to the areola, and spread of intraductal carcinoma (DCIS) (18).

4.1.1 Subcutaneous mastectomy

4.1.1.1 Skin sparing mastectomy (SSM)

In skin sparing mastectomy the surgeon removes the glandular breast tissue and nipple-areolar complex (NAC), but preserves the breast skin envelope intact for immediate breast

reconstruction with an implant or the patient's own tissue (6). Preservation of the skin envelope makes it possible to restore the natural shape of the breast and maintain breast symmetry (6). The incision is adapted to the shape and size of the breast, as well as the localization of the tumor. The skin envelope can be from mm to cm thick, but the aim is to have equal thickness and skin flaps that are well-circulated, without leaving glandular breast tissue behind (3).

4.1.1.2 Nipple-sparing mastectomy (NSM)

Nipple sparing mastectomy, also called total skin-sparing mastectomy, involves a complete removal of the glandular breast tissue, with the preservation of the breast skin and nipple-areola-complex, for immediate reconstruction (6, 12). This can be done by using a variety of incision techniques depending on if it is a therapeutic or prophylactic mastectomy (6). Inframammary (IMF) or infralateral incision is usually used in risk-reducing bilateral NSM, while in therapeutic NSM, tumor location must be taken into consideration to avoid positive margins (6). Positive margins means that there is carcinoma in situ or cancer infiltration on the resection edge (6) when histologically evaluating the breast tissue removed. NSM offer a better cosmetic result (19), higher level of breast satisfaction and a better body image than SSM (20). Also, combined with immediate reconstruction, the NSM technique has shown to not go on the expense of oncological safety (8, 21).

4.1.1.3 Hydrodissection

Hydrodissection, also called tumescent dissection, may make it easier for the surgeon to differ between the subcutaneous tissue belonging to the skin and the glandular breast tissue, and this way identify the dissection plane (22). A mixture of 1 liter lactated Ringer's solution, 30 milliliters (ml) of 1% lidocaine hydrochloride and 1 ml of dilute epinephrine is made (23), where approximately 200 ml is inserted in to the subcutaneous tissue over the entire breast. Then the breast tissue is dissected (24). Longer duration of breast reconstruction surgery is associated with an increase in early postoperative complications (25). The technique is fast (23, 26, 27) and reduces intraoperative bleeding during dissection (26), which may be a potential benefit to avoid postoperative complications. Also, it may improve skin flaps due to a better dissection plane, which may result in fewer revision surgeries (22).

4.1.2 Breast reconstruction

The breast reconstruction is done by filling the empty breast envelope with an breast implant, the patient's own tissue, or a combination of these (3). The breast reconstruction can be classified in the timing of the surgery and the type reconstruction method used, implant-based

or autologous with the patient's own tissue (17). Timing of the reconstructive surgery can be done immediately in the same operation or delayed after completion of adjuvant therapy (3). Further, the operation is planned as a one-stage or two-stage reconstruction (3).

4.1.2.1 Implant-based breast reconstruction (IBBR)

Implant-based breast reconstruction is the most frequent used reconstruction method (28). The implant is composed of an outer layer of silicone and is filled with saline or silicone (29). Further, the operation can be planned as a one-stage or two-stage reconstruction (3). In the case of a two-stage approach a tissue expander is being placed in the initial operation (3). Pending the secondary operation, the tissue expander is gradually filled with saline through a port until the desired breast size is reached (6). The filling is usually spaced with 2 weeks apart at UNN Tromsø. The tightness of the patient's skin has to be evaluated when deciding how much saline to fill (6). When the tissue expansion is finished, usually after three months, the tissue expander can be exchanged with a permanent implant (6, 30).

In the first attempts of implant-based reconstruction, the implants were placed directly under the skin, subcutaneously (31). This reconstruction was associated with high rates of complications (31) and therefore a change in the surgical technique was needed, leading the implant to be placed submuscular, under the muscles of the chest wall (32). Subpectoral placement of the breast implants prevents direct contact between the subcutaneous tissue and the breast implants and provides rich vascularization of the post-mastectomy skin (6). However, some patients develop complications like breast animation and pain due to muscle spasms after subpectoral breast reconstruction (33).

Placing the breast implants in the prepectoral space is being used with increasing popularity over submuscular placement and stands as the preferred approach when using immediate implant-based reconstruction with acellular dermal matrix (ADM) (6). ADM and synthetic meshes such as TIGR-matrix is often used to support the implant in the right position (3, 34). Compared to autologous reconstruction, breast reconstruction with implant is less invasive and has shorter operation time, but it is more difficult to receive a natural result (6). Breast reconstruction with implants have shown advantages such as low rates of early postoperative complications, but on the other hand, high rates of long term complications like capsular contracture and rupture of the implant (17). In addition, adjuvant radiation after implant-based reconstruction is shown to cause more wound healing problems, higher rates of capsular contracture, implant loss and reoperations (35).

4.1.2.2 Autologous reconstruction

When reconstructing with the patient's own tissue in an immediate breast reconstructive setting, the first choice is microsurgery with a free flap taken from the abdomen, called the deep inferior epigastric perforator (DIEP) (3, 17). In the procedure, the vascular stalk in the free flap is freely dissected from the abdominal muscles, reducing donor area morbidity and weakening of the abdominal wall (30). The vascular stalk in the gathered free flap is divided and connected to a corresponding vascular stalk in the recipient area (30), the mastectomy site of the breast. Free flaps are associated with increased morbidity after the operation and the procedure is only preformed if microsurgical competence is present at the plastic surgical department (3). Pedicled patches from the back, latissimus dorsi (LD) flaps, or from the chest, lateral thoracic artery perforator (LTAP) flap and the lateral intercostal artery perforator (LICAP) flap, can be considered used as an alternative to the DIEP flap (3).

Deciding if the patient is suited for the operation, ones should take physical limitations to consideration, like if there is enough tissue present (17). Flap harvesting is causing additional scars and autologous reconstruction has longer recovery time than implant-based reconstruction, making patients potentially decide against this reconstruction method (17). In addition, radiation can lead to a higher occurrence of scar formation and shrinkage of the skin flaps when used before an autologous reconstruction (36). However, when successfully, an autologous reconstruction is lifelong for the patient (3) and gives a more natural texture of the breast and aesthetical result than an implant (30).

4.2 Postoperative complications

Complications following subcutaneous mastectomy includes infection, wound dehiscence, seroma, hematoma, skin necrosis, nipple necrosis, asymmetry and chronic pain (6). Breast reconstruction related complications also include capsular contractures, implant malposition, implant loss, implant rupture, implant exposure, and donor-tissue-related complications when using the autologous technique (33).

Seroma is an accumulation of serous fluid under the skin (24). Left untreated it can lead to wound dehiscence, wound infection, flap necrosis, longer recovery time and a less aesthetic result (37). After mastectomy, the patient has an 2-11% overall risk of bleeding (6). The hematoma usually occurs within 12-24 hours postoperative and can usually be seen as a larger and tender breast (33). Postoperative infection can be presented as wound dehiscence,

erythema, or drainage from the wound (6). It is treated with oral or intravenous antibiotics, or a removal of the implant (6).

Skin flap necrosis happens when it is not enough blood supply to the flap, causing the skin to die, which can further lead to infection and wound dehiscence (6). The necrosis can be partial or total, and when is only partial, it can be treated conservatively with Silvadene ointment (6). However, if the necrosis has reached the full thickness of the flap, removal of the necrosis and a cover over the defect may be necessary (6). For nipple necrosis, conservative treatment is often enough for most of the partial nipple necrosis and some of the complete nipple necrosis (38). However, the nipple-areola complex must be excised if full-thickness nipple necrosis develops (6). Capsular contracture is the most common complication after implant-based reconstruction (39) and comes from the formation of fibrous tissue around the implant (33). When it is evaluated in studies, usually only capsular contracture graded as Baker grade 3-4 are included as a complication (33).

4.3 Aim

The aim of this study is to see if changes made in the surgical technique, including the implementation of vertical incision, hydrodissection and prepectoral breast reconstruction, has led to a reduction in postoperative complications following subcutaneous mastectomy with immediate breast reconstruction at UNN Tromsø in the five-year period from 2017-2021.

5 Material and methods

5.1 Study design and population

The study is a retrospective observational study for quality assurance at the Department of Urology, Breast and Endocrine- and Plastic and Reconstructive surgery at UNN Tromsø. It was completed as a Master thesis in Medicine at UiT the Arctic University of Norway. The study population contains all patients having undergone subcutaneous mastectomy with immediate breast reconstruction in the five-year period from January 2017 to December 2021 at UNN Tromsø. That includes a total of 87 patients (137 breasts) operated for invasive cancer, intraductal carcinoma (DCIS) and prophylactic due to BRCA mutation or previous breast cancer in contralateral breast.

5.2 Data collection

The data was collected retrospective from the patient's electronic journal in DIPS (Distributed Information and Patient Data System in Hospitals) at UNN Tromsø. This included data from the patient's admission note, outpatient note, medical record written by nurses or health care assistants at the hospital ward, operation description, operation note, interdisciplinary note and discharge summary. All data was collected by the student. The gathering started in January 2022 and was completed in April 2022.

5.3 Variables

Patient characteristics

- Age at date of primary operation
- BMI (kg/m^2) calculated from weight and height
- Risk factors (Obesity ($\text{BMI} \geq 30$), smoking, hypertension, diabetes, previous breast surgery, previous radiation therapy, adjuvant radiation, adjuvant chemotherapy)
- Indication for surgery: cancer, DCIS, BRCA or other (prophylactic due to familial disposition or prophylactic due to prior breast cancer in contralateral breast)
- Bilateral- or unilateral breast surgery

Operation details

- Mastectomy technique (NSM or SSM, use of hydrodissection)
- Mastectomy incision technique (vertical, periareolar/circumareolar, lazy S, inframammary (IMF)/ inferolateral, wise-pattern, or other including radial lateral, horizontal elliptical, vertical elliptical and incision in scar from previous breast surgery)
- Type of breast reconstruction (implant-based or autologous), one- or two-staged reconstruction
- Type of implant placement (prepectoral or subpectoral)
- Use of tissue expander and use of surgical mesh (TIGR-matrix or ADM)
- Weight of specimen removed in grams
- Initial implant volume in milliliters (ml) and initial tissue-expander volume in ml
- Operation time in minutes

Primary outcome

- The primary outcome is the number of postoperative complications after the primary operation and what kind of complications that occur most frequently. Inspired by Sood et al (40) and the previous master thesis (1) the complications were divided into early- and late postoperative complications. Early postoperative complications are within 30 days after the primary operation. Late postoperative complications are limited to complications occurring 30 days after the primary operation, and before the secondary operation (for those operated with two-stage breast reconstruction).
- Early postoperative complications
 - Infection requiring oral or intravenous antibiotics
 - Hematoma
 - Seroma
 - Wound dehiscence
 - Skin flap necrosis, including partial- or full-thickness necrosis
 - Nipple necrosis
- Late postoperative complications
 - Implant malposition
 - Implant rupture
 - Capsular contracture with Baker grade 3-4 (41)

Secondary outcome

- To get a closer look at the additional burden postoperative complications and this type of surgery may have for the patients, the secondary outcome was reoperations due to complications following the primary operation and other surgery needed after the primary- or secondary operation to obtain an aesthetic favorable result.
- Reoperation due to complications
 - Wound revision
 - Hematoma evacuation
 - Capsulotomy
 - Implant removal with or without exchange to new implant/tissue expander
- Other surgery needed to obtain an aesthetic favorable result
 - Fat transplantation, mastopexy and breast reduction

5.4 Statistical analysis

Descriptive statistics were used for presenting patient characteristics, operation details and surgical outcome. Where number, percent, mean, median, 95% confidence interval (CI) and interquartile range (IQR) was used in the description. Pearson Chi Square was used when comparing the group of breasts operated with and without hydrodissection (HD), and between groups of breasts reconstructed with prepectoral- and subpectoral implant placement. The statistical software program Statistical Package for the Social Sciences (SPSS) version 28 was used to analyze data, where p-value < 0,005 was considered significant. All the statistical analysis was done by the student.

5.5 Formal applications and approvals

The study is approved as a quality assurance study by the data protection officer at UNN Tromsø, with project number 02704. Since it is a quality assurance study, there was no need to submit it to regional committees for medical and health research ethics (REK). No funding was received.

6 Results

6.1 Patient characteristics

A total of 87 patients (137 breasts) were included, with a mean age of 47 years and mean BMI of 24,8 km/m². Overall, 50 patients were operated bilateral and 37 unilateral. Indication for surgery were invasive cancer for 33 (32%) breasts, BRCA mutation for 46 (45%), DCIS for 21 (20%) and prophylactic due to anxiety because of prior breast cancer in contralateral breast for 3 (3%) breasts.

In patient factors associated with higher risk for postoperative complications, 8 (9%) were obese, 3 (3%) were smokers, 3 (3%) had hypertension, 1 (1%) had diabetes, 23 (26%) had previous breast surgery in operated breast, 10 (11%) had previous radiation, 9 (10%) had received adjuvant radiation and 12 (13%) had adjuvant received chemotherapy. Patient characteristics are listed in Table 1.

6.2 Operative details

Operative details are listed in Table 2. In a total of 137 breasts, there were 32 (23%) SSM and 105 (77%) NSM. In 81 (59%) breasts the hydrodissection (HD) technique was used in addition to SSM or NSM and between 85-96% of the operations from 2019 onwards were performed

using HD. The mastectomy incision types used included vertical, periareolar/circumareolar, lazy S, IMF/inferolateral, wise pattern, and others. Vertical incision was used most frequently and was used in 55 (50%) breasts. Followed by IMF/inferolateral in 34 (25%), wise pattern in 14 (10%), periareolar/circumareolar in 13 (10%), lazy S in 10 (7%) and other in 10 (7%). Others included incision in scar from previous breast surgery, radial lateral incision, horizontal elliptical and vertical elliptical incision. Illustration of the incisions used is shown in Figure 1.

Two-stage reconstruction with a temporary tissue expander was the most common method for immediate breast reconstruction and was used in 77 (56%) breasts. One-stage autologous reconstruction was used in 9 (7%) and one-stage implant-based reconstruction in 49 (36%). The breast implants, including permanent implant and tissue expander, were placed prepectoral in 107 (78%) breasts and subpectoral in 21 (15%) breasts. In the reconstruction there was used additional mesh such as TIGR-matrix in 24 (17%) breasts and ADM in 1 (1%) breast. The operation time ranged from 58-691 minutes, with a mean of 196 minutes. Median weight of specimen removed under the initial operation was 400 grams. Mean initial implant volume was 367 ml and mean initial tissue expander volume was 182 ml.

6.3 Surgical outcomes and postoperative complications

Details of the early- and late postoperative complications following the initial operation of subcutaneous mastectomy with immediate reconstruction are listed in Table 3. In total, 42 (48%) patients developed postoperative complications following their initial operation, which corresponds to 44 (32%) breasts. Development in overall postoperative complication rate during 2017-2021 is shown in Figure 2 and development in early postoperative complications is shown in Figure 3. The analyses showed no significant change in the rate of early postoperative complications over the period.

Overall, the most frequent complication was seroma, which occurred in 19 (14%) breasts. Followed by hematoma in 15 (11%), skin flap necrosis in 11 (8%), nipple necrosis in 9 (7%), infection that required oral or iv. antibiotics in 7 (5%) and wound dehiscence in 4 (3%). Forty-two (31%) developed early complications (within 30 days after surgery) and 3 (2%) developed late complications. In the late complications, 3 (2%) developed capsule contracture, 1 (1%) rupture of the tissue expander and none of the breasts implant malposition. Mean follow up time was 172 days, with a range from 31 to 667 days. During this time one of the patients operated for invasive cancer died due to cancer recurrence. Also, one of the patients operated for BRCA, developed breast cancer metastasis and is now under palliative treatment. Nine

breasts are not completely reconstructed. Of these, seven breasts operated with two-stage tissue expander are waiting for the secondary operation and one patient operated bilateral chose to not have any further reconstruction due to complications.

6.3.1 Hydrodissection versus no hydrodissection

When comparing the group of breasts operated with hydrodissection and without hydrodissection, there was a significant difference. The mastectomies done without the use of HD had a significantly higher rate of skin flap necrosis than the mastectomies where the HD technique was used. There was no significant difference between the two groups when it came to infection requiring oral/iv. antibiotics, seroma, hematoma, wound dehiscence, and nipple necrosis. Also, there was no significant difference between the two groups regarding late postoperative complications including capsular contracture, rupture of the implant or tissue expander, or implant malposition. The comparison between HD and no HD is listed in detail in Table 4.

6.3.2 Prepectoral versus subpectoral implant placement

When comparing the group of breasts reconstructed with the breast implant placed prepectoral, with the group of breasts reconstructed with subpectoral placement, we could not find a significant difference for early postoperative complications including infection requiring oral/iv. antibiotics, seroma, hematoma, wound dehiscence, skin flap necrosis and nipple necrosis. Also, there was no significant difference between the two groups regarding late postoperative complications including capsular contracture, rupture of the implant or tissue expander, or implant malposition. The comparison between prepectoral and subpectoral breast implant placement is listed in detail in Table 5.

6.4 Reoperations and aesthetic concern

Reoperations due to postoperative complications following the primary- or secondary operation are listed in Table 6. Twenty-nine (21%) of the patients, corresponding to 57 (42%) breasts, needed one or more reoperations. The most frequent reoperation was implant removal without exchange to a new implant, which occurred in 19 (14%) breasts. Followed by capsulotomy in 15 (11%), wound revision in 9 (7%), hematoma evacuation in 8 (6%) and implant removal with exchange to new implant or TE in 1 (1%). Additional surgery needed to obtain an aesthetic favorable result are listed in Table 7. A total of 43 (31%) breasts needed one or more additional surgeries, where 31 (23%) breasts had one or more fat transplantations, 5 (4%) had mastopexy

and 7 (5%) had breast reduction. In addition, 17 (12%) breasts developed rippling of the breast, where 8 of these breasts needed a fat transplantation because of the rippling.

7 Discussion

The purpose of this study was to see if the changes made in the surgical technique at UNN Tromsø led to a reduction in postoperative complications following subcutaneous mastectomy with immediate breast reconstruction. The changes included implementation of vertical incision, hydrodissection and prepectoral breast reconstruction. The analyzes showed that 32% of the breasts developed postoperative complications during 2017-2021. This is a reduction from the complication rate of 56% in the previous master thesis (1). Vertical incision was the most used incision, being used in 50% of the breasts. The study found that breasts operated without the hydrodissection technique had a significantly higher rate of skin flap necrosis. However, no significant difference was found when comparing prepectoral and subpectoral breast reconstruction. Finally, because of the complications, 42% of the breasts needed reoperations and 31% needed one or more additional surgeries to obtain a favorable result.

7.1 Postoperative complications

Patient factors shown to increase the risk of complications after subcutaneous mastectomy with immediate reconstruction are high BMI and older age (42, 43), plus large breasts, and therefore high weight of specimen removed, which is associated with higher risk for ischemic complications (44, 45). Compared to the previous thesis there was a great similarity between the study population in terms of age, BMI, indication for surgery, weight of specimen removed and risk factors for complications such as diabetes and previous surgery in the operated breast (1). This study is therefore well suited to compare the rate of postoperative complications found with those reported in the previous thesis.

The National Quality Register for breast cancer in Norway does not report complication rates after subcutaneous mastectomy with immediate reconstruction, only collected for all types of breast surgery (46). In addition, there are variations in the offer of immediate reconstruction over the country (46). This makes it difficult to compare our results directly to complication rates at other hospitals in Norway, but also addresses the importance of establishing the complication rate after this type of surgery in a nationwide registry in the future.

Clavien-Dindo classification for surgical complications is a validated severity scale that uses intervention required to address complication severity objectively (47). When evaluating

complications following breast reconstruction it may be beneficial to use an similar approach (48). Standardized definition of complications and classification of severity gives a more accurate evaluating of complication rates and makes it easier to compare studies with each other (48). However, to the best of our knowledge, only a few studies involving breast surgery (49-51) have used the Clavien-Dindo classification (47) to evaluate surgical complications.

As the primary outcome of the study, we found that 32% breasts developed one or more complications. Compared to the previous master thesis (1) were 56% of the breasts developed complications, the results show a reduction in the overall complication rate. Elsewhere the complication rate is reported to be up to approximately 50% (52). A single-institution retrospective review including 500 NSM over five years, found a lower complication rate of 12% (53) compared to our study. In contrast to our study, the retrospective review (53) did not include wound dehiscence or capsular contracture, which may be a reason for the different rates.

Seroma is the most frequent complication after breast surgery (54) and was also the most common complication in our study. According to the National Quality Register for breast cancer in Norway, the incidence of postoperative complications following breast surgery is low (46). Rates of hematoma after breast surgery is reported to be 2% nationwide (46), < 5 % after NSM (6), and between 2% to 11% after mastectomy (55), which is consistent with the rate of 11% found in our study. A possible reason our study had a higher hematoma rate than what is reported nationwide, may be because we have reviewed the entire medical record for each patient, which may ensure a more completeness of the data on complications. The proportion of infections requiring antibiotics was 5% in our study and were similar compared to nationwide numbers of 5% after breast surgery (46).

Incision location affects both nipple necrosis rates and overall complication rates (56). Periareolar incision and inframammary incision is shown to increase the nipple necrosis rate with 17% and 9% (6). There is increase in the overall complication rate from 21% in 2017 to 32% in 2018, and a possible reason for that may be that IMF/inferolateral incision was being used in nearly 70% of the breast operated in 2018. Also, a possible reason for the high overall complication rate in 2019, may be because most of the mastectomies where periareolar incision was used occurred in 2019. Vertical incision was the most used incision technique in our study and has been shown not to be associated with increased complications or skin flap necrosis (57), meaning that the implementation of the incision may have had an impact in the reduction of the overall postoperative complication rate.

Skin flap necrosis is defined in various ways in the literature (58), from, among other things, how deep the necrosis goes to tissue affection, making the incidence reported range from 2-40% in various studies (48, 59, 60). This makes it challenging to compare our incidence of skin flap necrosis with other studies in the literature. However, compared to the previous thesis (1), it is safe to say that our incidence of 8% is fairly lower than the previous reported incidence of 37%. A scoring system for severity of skin flap necrosis called SKIN score was introduced in 2015, where the score is set by post-operative visual examination of photographs (61). However, the scoring system has so far been little used and may be limited when applied in clinical practice due to its complexity (48). In a recent study, Oleck et al proposes a simplified intervention-based classification system where skin flap necrosis is classified based on intervention required (48). Stating that the classification is easily adopted and that the information needed is probably available in the patients' medical record, and therefore should be implemented in future studies (48).

Implant-based reconstruction is associated with late complications like capsular contracture (17). The study reports low rate of capsular contracture (1%) similar to the previous thesis (3%) (1). Capsular contracture usually appears after 12 months and the cumulative risk for contracture is shown to be greater the longer the implants are in (62, 63). Since this study include patients from 2021, the patients operated late that year had a short follow-up time, which may lead to the low reported rate of capsular contracture in our study. Placing the breast implant in the prepectoral space is shown to have advantages such as lower rates of Baker grade 3-4 capsular contracture, lack of breast animation and less pain for the patient (6). The study did not find a significant difference for postoperative complications when comparing prepectoral- and subpectoral breast implant placement. Similar was found in a retrospective review on 405 NSM with either prepectoral- or subpectoral implant placement (64). The same study found that prepectoral placement was associated with significantly reduced mastectomy skin flap necrosis (64). A possible reason we didn't find a significant difference regarding skin flap necrosis and prepectoral placement in our study, may be because our study-set had few breasts for comparison of the breast implant placement and that only a small group of breasts had the implants placed subpectoral.

Comparing the group of breasts operated with hydrodissection (HD) and without, the study showed that the breasts operated without the HD had a significantly higher rate of skin flap necrosis than the mastectomies where the HD technique was used. Combined with the fact that the incidence of skin flap necrosis in our study was much lower (8%) than reported in the

previous thesis (37%) (1), this may indicate that HD have been a contributing factor for the reduction in the overall complication rate in this study. The literature shows variable results regarding whether the HD technique combined with immediate breast reconstruction decreases or increases skin necrosis (27, 65, 66). Some retrospective studies have found HD to be associated with increased risk of skin flap necrosis when used in an immediate reconstructive setting (65, 66). However, a large retrospective review of 1491 breasts found no significant association between neither seroma, hematoma, infection or skin flap necrosis and the use of the HD technique (27).

7.2 Reoperations and additional surgery

As the secondary outcome of the study, 42% of the breasts needed reoperations because of the complications and 31% of the breasts needed one or more additional surgeries to get a cosmetic favorable result. Removal of the implants can happen as a result of delayed healing due to postoperative complications (33). More breasts in our study had implant removal (14%) than the previous thesis (11%) (1), and the rate is also higher than what's reported in an another retrospective study of 87 patients undergoing subcutaneous mastectomy with immediate reconstruction (12%) (40).

Capsular contracture often leads to reoperation because of pain to the patient (30). In our study, capsulotomy due to capsular contracture was only needed for one breast. As previously mentioned, the capsular contracture usually occurs after 12 months (63), which makes it possible that more capsular contracture, and thus more reoperations with capsulotomy would possibly have taken place if the study had a longer follow-up time. However, a capsulotomy performed simultaneously in the second operation where the tissue-expander was exchange to a permanent implant or reconstructed with the patient's own tissue, was necessary in 14 breasts.

Breast reduction and mastopexy are included in aesthetic breast surgery (33). Mastopexy was performed in 4% of the breasts and 5% of the breasts had breast reduction. In fat transplantation, fat is harvested from a place on the patient's body that has excessed fat, then centrifuged and cleaned before it is placed in the patients breast (3). Fat transplantation can enhance the final aesthetic result after prepectoral reconstruction by increasing the thickness of the soft tissue flaps and minimize the visibility of the implant (6, 67). The procedure has low rates of complications and has advantages in that the patient's own tissue is being used (3). In our study, 23% of the breasts had one or more fat transplantation and 8 of these was due to rippling. Rippling of the implant means that irregularities is shown in the skin due to the implant being

visible through the breast tissue and is more common in prepectoral implant reconstruction (33). We found that 12% of the breasts developed rippling, while rippling was not mentioned as a concern in the previous thesis (1). Since more breasts were reconstructed with the implant placed prepectoral (78%) compared to subpectoral (15%) in our study, the rate of rippling seems reasonable.

7.3 Strengths and limitations

There are mainly three strengths in this study. One of the strengths is that it is based on data from 138 breasts, collected from a total of five years. The study included all patients who underwent subcutaneous mastectomy with immediate reconstruction and therefore represent the quality and practice of this type of surgery at UNN Tromsø. In addition, patients in the study were unselected due to the retrospective study design.

Limitations of the study are that confounding factors like age and adjuvant therapy were not adjusted, leading a potential of confounding bias. Some data was missing for smoking, which can lead to information bias. The data was collected by only one researcher, a 5th year medical student with interest in the field, and not a certified surgeon. This can lead to both subjective assessment of the study since it was only one collector, as well as misconceptions due to lack of experience in breast surgery. When comparing the reconstruction technique and postoperative complications, there was a numeric disparity between the breast that had the breast implant placed prepectoral versus subpectoral. The follow-up time in this study ranged from 31 to 667 days. Since the study has included patients operated in 2021, the data collection from the patients operated late that year only includes late postoperative complications and reoperations that occurred within 5 months. This is an important limitation on the number of postoperative complications, reoperations, and additional surgery. Also limiting an important outcome for breast cancer treatment such as overall survival.

7.4 Implementations of the study and further work

The thesis provides insight into the overall postoperative complication rate following subcutaneous mastectomy with immediate breast reconstruction at UNN Tromsø, and possible reasons for the complications. By looking at the proportion of reoperations and additional surgeries needed to obtain a favorable aesthetic result, the study also addresses the burden this type of breast surgery may have on these patients.

The incident of postoperative complications is commonly used as a performance indicator for the quality of the surgical cancer treatment (68). This thesis shows that the implementation of the HD technique and vertical incision may have reduce the incidence of postoperative complications following subcutaneous mastectomy with immediate breast reconstruction, and thus increased the quality of the breast cancer treatment. Together with the previous master thesis (1), this study can contribute to a possible national register or a register at UNN Tromsø that documents postoperative complications following this type of breast surgery.

This thesis investigated postoperative complications limited to only include those occurring after the primary operation and before the secondary surgery. Further work should include complications following the secondary surgery and donor-tissue-related complications after autologous reconstruction as well. A larger number of patients should be considered when comparing groups of breasts reconstructed with prepectoral- and subpectoral implant placement. In addition, further work should concern a histological evaluation of the surgical margin, to quality assure that the changes in the surgical technique haven't gone on the expense of the breast cancer treatment.

8 Conclusion

A reduction in postoperative complications was found after the changes were made in the surgical technique. Vertical incision was used most frequent, and breasts operated without the hydrodissection technique had a significantly higher rate of skin flap necrosis, indicating that hydrodissection and vertical incision may have had a contributing factor to the reduction. No significant difference in complication were found when comparing prepectoral and subpectoral breast reconstruction.

The complications resulted in 42% of the breasts needing reoperations and 31% of the breasts needed one or more additional surgeries to obtain a favorable cosmetic result. The study provides insight into the quality and practice of this type of surgery at UNN Tromsø and addresses the burden this surgery may have on these patients. Finally, larger patient groups should be used when comparing subpectoral and prepectoral breast reconstruction, and longer follow-up time is needed to address the extent of late postoperative complications, reoperations and additional surgery needed.

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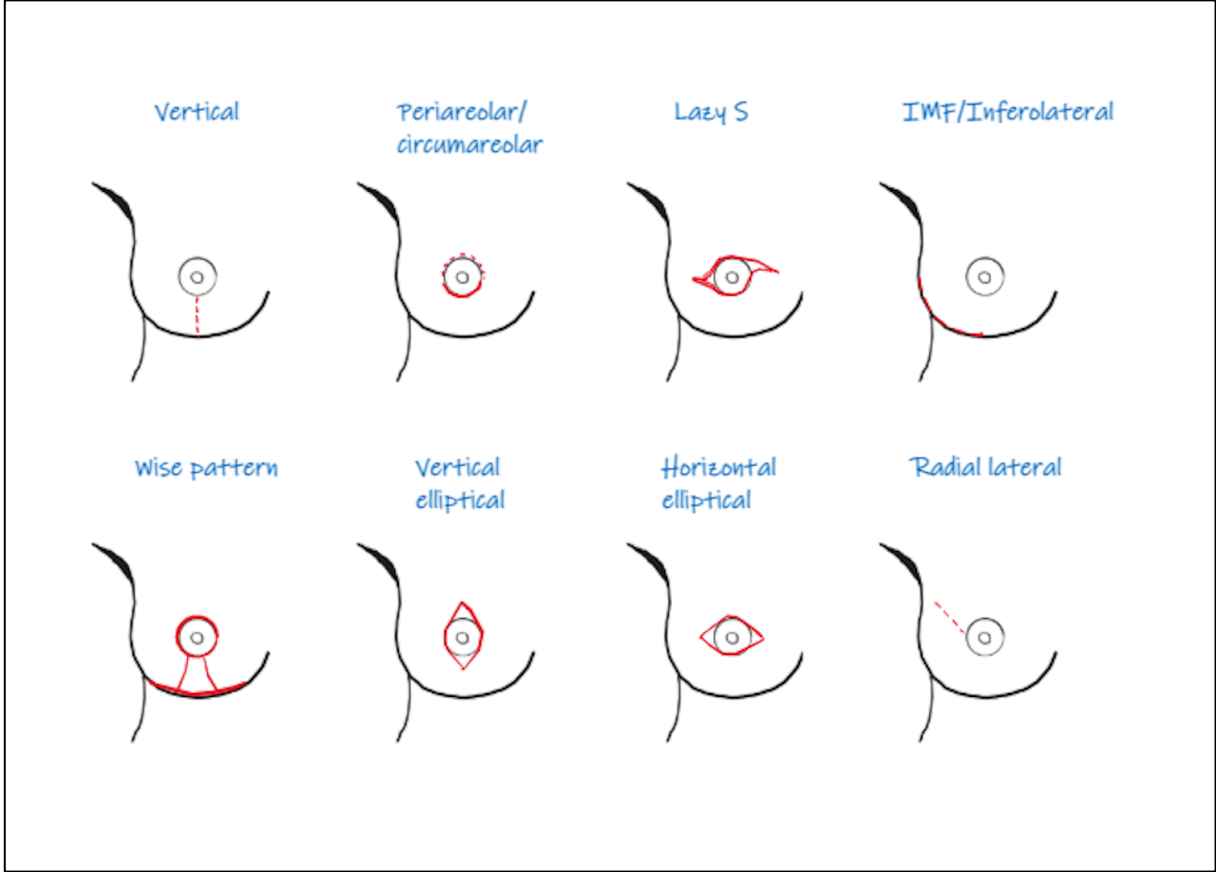
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Figures

Figure 1: Illustration of the incision's techniques used in subcutaneous mastectomy with immediate reconstruction during 2017-2021 at UNN Tromsø. (Made by the author)



Abbreviation: IMF, inframammary.

Figure 2: Development in overall postoperative complication rate after subcutaneous mastectomy with immediate breast reconstruction, during 2017-2021.

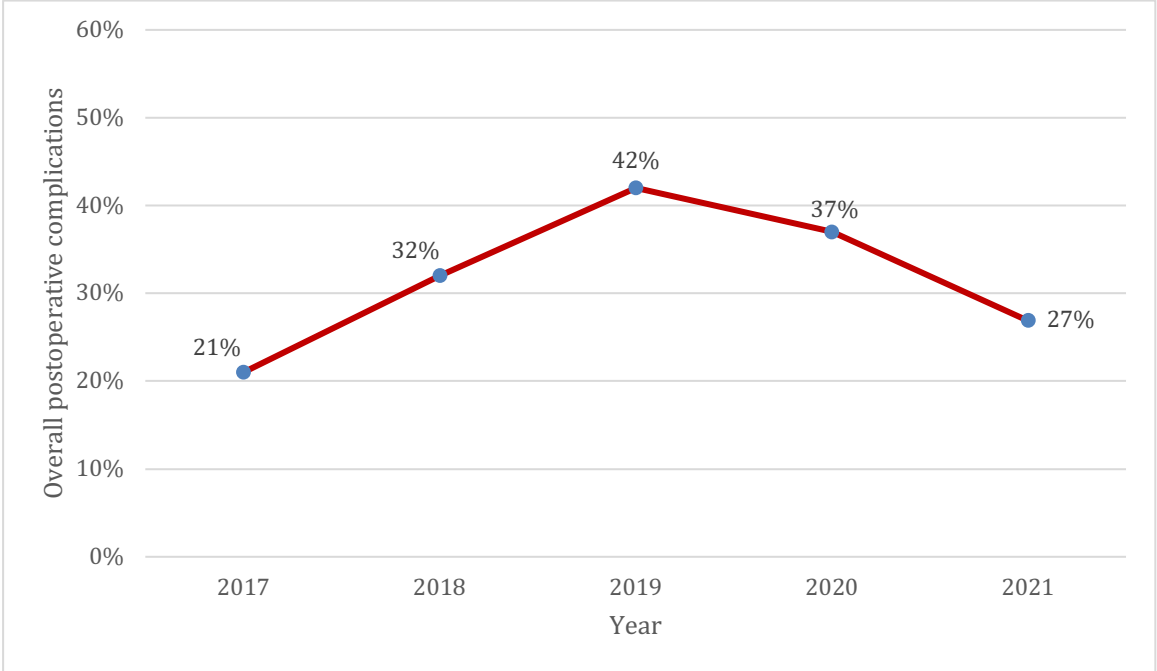
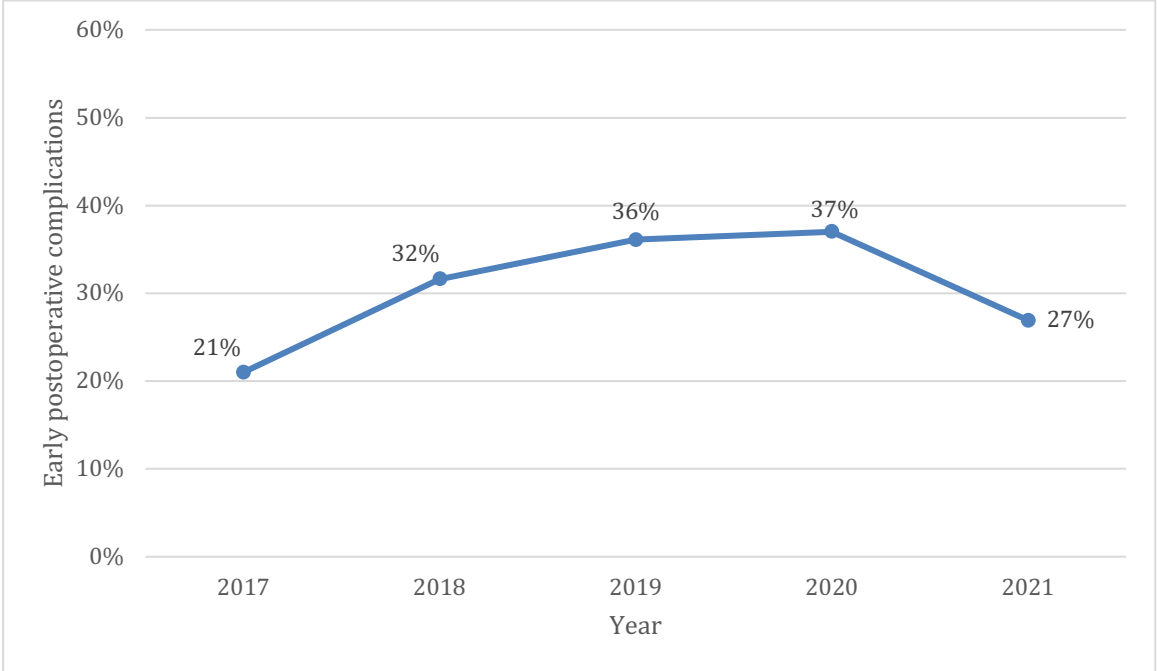


Figure 3: Development in early postoperative complication rate (within 30 days) after subcutaneous mastectomy with immediate breast reconstruction, during 2017-2021.



Tables

Table 1: Characteristics of 87 patients that underwent subcutaneous mastectomy with immediate breast reconstruction in the five-year period 2017-2021 at UNN Tromsø.

		N (%)	Mean	Range	Median	95% CI
Age (years)		87 (100%)	47	27-68	48,0	45 – 49
BMI (km/m²)		87 (100%)	24,8	19,0-34,2	24,1	24,1-25,6
Risk factors for complications	Obesity (BMI ≥ 30)	8 (9,2%)				
	Smoking¹	3 (3,4%)				
	Hypertension	3 (3,4%)				
	Diabetes	1 (1,1%)				
	Previous breast surgery²	23 (26,4%)				
	Previous radiation	10 (11,5%)				
	Adjuvant radiation	9 (10,3%)				
	Adjuvant chemotherapy	12 (13,8%)				
Bilateral breast surgery	Yes	50 (57,5%)				
	No	37 (42,5%)				
Indication for surgery³	N (%)	103 (100%)				
	Invasive breast cancer	33 (32,0%)				
	BRCA mutation	46 (44,7%)				
	DCIS	21 (20,4%)				
	Previous breast cancer in contralateral breast	3 (2,9%)				

¹: There were missing data for smoking in n=5 patients.

²:23 patients had undergone one or more previous surgery in the operated breast, including BCS (n=19), breast augmentation (n=5), breast reduction (n=1) and reoperation due to complications following BCS (n=1).

³:15 patients had two or more indications for surgery, therefore the total amount of indication for surgery is 103. Abbreviations: BMI, body mass index; DCIS, intraductal carcinoma; BRCA, breast cancer gene; BCS, breast-conserving surgery.

Table 2: Operative details for 137 breast that underwent subcutaneous mastectomy with immediate breast reconstruction during 2017-2021.

		Total n=137	2017 n=29	2018 n=19	2019 n=36	2020 n=27	2021 n=26
Mastectomy technique	SSM n (%)	32 (23,4%)	10 (34,5%)	0 (0%)	10 (27,8%)	3 (11,1%)	9 (34,6%)
	NSM n (%)	105 (76,6%)	19 (65,5%)	19 (100%)	26 (72,2%)	24 (88,9%)	17 (65,4%)
	With use of HD n (%)	81 (59,1%)	0 (0%)	0 (0%)	33 (91,7%)	26 (96,3%)	22 (84,6%)
Mastectomy incision¹	Vertical n (%)	55 (50,1%)	0 (0%)	1 (5,2%)	20 (55,5%)	24 (88,9%)	10 (38,5%)
	Periareolar/Circumareolar n (%)	13 (9,5%)	3 (10,3%)	0 (0%)	7 (19,4%)	0 (0%)	3 (11,5%)
	Lazy S n (%)	10 (7,3%)	4 (13,8%)	2 (10,5%)	0 (0%)	0 (0%)	4 (15,4%)
	IMF/Inferolateral n (%)	34 (24,9%)	14 (48,3%)	13 (68,4%)	5 (13,9%)	0 (0%)	2 (7,7%)
	Wise pattern n (%)	14 (10,2%)	6 (20,7%)	3 (15,8%)	0 (0%)	0 (0%)	5 (19,2%)
	Other* n (%)	10 (7,3%)	1 (3,4%)	0 (0%)	5 (13,9%)	2 (7,4%)	2 (7,7%)
One-stage reconstruction	Total n (%)	60 (43,8%)	19 (65,5%)	10 (52,6%)	9 (25%)	11 (40,7%)	11 (42,3%)
	Implant based n (%)	51 (37,2%)	19 (65,5%)	4 (21,0%)	6 (16,7%)	11 (40,7%)	11 (42,3%)
	Autologous (DIEP)² n (%)	9 (6,6%)	0 (0%)	6 (31,6%)	3 (8,3%)	0 (0%)	0 (0%)
Two-stage reconstruction with tissue expander	n (%)	77 (56,2%)	10 (34,5%)	9 (47,4%)	27 (75%)	16 (59,3%)	15 (57,7%)
Implant placement	Prepectoral n (%)	107 (78,1%)	10 (34,5%)	11 (57,9%)	33 (91,7%)	27 (100%)	26 (100%)
	Subpectoral n (%)	21 (15,3%)	19 (65,5%)	2 (10,5%)	0 (0%)	0 (0%)	0 (0%)
Use of surgical mesh	TIGR-matrix n (%)	24 (17,5%)	7 (24,1%)	2 (10,5%)	4 (11,1%)	6 (22,2%)	5 (19,2%)
	ADM n (%)	1 (0,7%)	1 (3,4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Weight of specimen removed³, grams	Mean	428,8					
	Range	79-1480					
	Median	400					
Initial implant volume, ml	Mean	366,5					
	Range	150-620					
	Median	355					
Initial tissue-expander volume, ml	Mean	182,2					
	Range	60-450					

	Median	150					
Operation time, minutes	Mean	196,4					
	Range	58-691					
	Median	171					

¹: Mastectomy incision were missing for n=2 breasts.

*: Other include incision in scar from previous breast surgery with either BCS or breast reduction (n=5), radial lateral (n=1), horizontal elliptical (n=3) and vertical elliptical (n=1).

²: In addition to the DIEP, a LICAP-flap was used when reconstructing one of the breasts.

³: The weight of specimen removed were missing for n=22 breasts.

Abbreviations: SSM, skin-sparing mastectomy; NSM, nipple-sparing mastectomy; HD, hydrodissection; IMF, inframammary; DIEP, deep inferior epigastric perforator; LICAP, lateral intercostal artery perforator; TIGR-matrix, synthetic surgical mesh; ADM, acellular dermal matrices ; BCS, breast-conserving surgery.

Table 3: Postoperative complications following the primary operation of subcutaneous mastectomy with immediate breast reconstruction on 137 breasts.

		Total n=137	2017 n=29	2018 n =19	2019 n =36	2020 n =27	2021 n =26	
Early postoperative complications (< 30 days)	Total¹	n (%)	42 (31,0%)	6 (20,7%)	6 (31,6%)	13 (36,1%)	10 (37,0%)	7 (26,9%)
	Infection requiring oral/iv. antibiotics	n (%)	7 (5,1%)	1 (3,4%)	3 (15,8%)	1 (2,8%)	1 (3,7%)	1 (3,8%)
	Seroma	n (%)	19 (13,9%)	2 (6,9%)	1 (5,3%)	7 (19,4%)	6 (22,2%)	3 (11,5%)
	Hematoma	n (%)	15 (10,9%)	3 (10,3%)	2 (10,5%)	4 (11,1%)	2 (7,4%)	4 (15,4%)
	Wound dehiscence	n (%)	4 (2,9%)	0 (0%)	0 (0%)	2 (5,6%)	2 (7,4%)	0 (0%)
	Skin flap necrosis²	n (%)	11 (8%)	4 (17,8%)	5 (26,3%)	1 (2,8%)	1 (3,7%)	0 (0%)
	Nipple necrosis	n (%)	9 (6,6%)	1 (3,4%)	2 (10,5%)	2 (5,6%)	1 (3,7%)	3 (11,5%)
Late postoperative complications (> 30 days)	Total	n (%)	3 (2,2%)	0 (0%)	0 (0%)	3 (8,3%)	0 (0%)	0 (0%)
	Capsular contracture³	n (%)	2 (1,4%)	0 (0%)	0 (0%)	2 (10,5%)	0 (0%)	0 (0%)
	Implant/TE rupture	n (%)	1 (0,7%)	0 (0%)	0 (0%)	1 (2,8%)	0 (0%)	0 (0%)
	Implant malposition	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Overall postoperative complication rate¹	n (%)	44 (32,1%)	6 (20,7%)	6 (31,6%)	15 (41,7%)	10 (37,0%)	7 (26,9%)	
Follow-up time (days)	Mean		172					
	Range		31-667					
	Median		146					

¹The total number of breasts with early postoperative complications and the overall postoperative complication rate is smaller than the frequency of the listed complications, due to some of the breasts having multiple complications following the surgery.

²Skin flap necrosis including both partial- or full-thickness necrosis.

³Capsular contracture for Baker grade 3-4 (41).

Abbreviations: TE, tissue expander; iv., intravenous.

Table 4: Comparison of postoperative complications in breasts operated with subcutaneous mastectomy with immediate reconstruction, with or without the use of hydrodissection (HD), during 2017-2021.

			n=137	HD (n= 81)	Without HD (n=56)	P-value
Early postoperative complications (< 30 days)	Total¹	n (%)	42 (30,4%)	28 (34,6%)	14 (25,0%)	0.232
	Infection requiring oral/iv. antibiotics	n (%)	7 (5,1%)	3 (3,7%)	4 (7,1%)	0.369
	Seroma	n (%)	19 (13,8%)	14 (17,3%)	5 (8,9%)	0.164
	Hematoma	n (%)	15 (10,9%)	10 (12,3%)	5 (8,9%)	0.529
	Wound dehiscence	n (%)	4 (2,9%)	4 (4,9%)	0 (0%)	0.091
	Skin flap necrosis²	n (%)	11 (8,0%)	2 (2,5%)	9 (16,1%)	0.004
	Nipple necrosis	n (%)	9 (6,5%)	6 (7,4%)	3 (5,3%)	0.634
Late postoperative complications (> 30 days)	Total	n (%)	3 (2,2%)	2 (2,5%)	1 (1,8%)	0.788
	Capsular contracture³	n (%)	2 (1,4%)	1 (1,2%)	1 (1,8%)	0.791
	Implant/TE rupture	n (%)	1 (0,7%)	1 (1,2%)	0 (0%)	0.404
	Implant malposition	n (%)	0 (0%)	0 (0%)	0 (0%)	

P < 0.005 was considered statistically significant.

¹The total number of breasts with early postoperative complications is smaller than the frequency of the listed early postoperative complications, due to some of the breasts having multiple early postoperative complications following the surgery.

²Skin flap necrosis including both partial and total necrosis.

³Capsular contracture for Baker grade 3-4 (41).

Some breast may had more than one complication.

Abbreviations: TE, tissue expander; HD, hydrodissection; iv., intravenous.

Table 5: Comparison of early- and late- postoperative complications following subcutaneous mastectomy with immediate reconstruction, in breasts that were reconstructed with the breast implant placed prepectoral versus subpectoral, during 2017-2021.

			n=128	Prepectoral (n=107)	Subpectoral (n=21)	P-value
Early postoperative complications (< 30 days)	Total¹	n (%)	38 (29,7%)	35 (32,7%)	3 (14,3%)	0.091
	Infection requiring oral/iv. antibiotics	n (%)	5 (3,9%)	4 (3,7%)	1 (4,8%)	0.825
	Seroma	n (%)	19 (14,8%)	17 (15,9%)	2 (9,5%)	0.453
	Hematoma	n (%)	14 (10,9%)	12 (11,2%)	2 (9,5%)	0.820
	Wound dehiscence	n (%)	3 (2,3%)	3 (2,8%)	0 (0%)	0.437
	Skin flap necrosis²	n (%)	6 (4,7%)	5 (4,7%)	1 (4,8%)	0.986
	Nipple necrosis	n (%)	8 (6,2%)	7 (6,5%)	1 (4,8%)	0.758
Late postoperative complications (> 30 days)	Total	n (%)	3 (2,3%)	3 (2,8%)	0 (0%)	0.437
	Capsular contracture³	n (%)	2 (1,6%)	2 (1,9%)	0 (0%)	0.528
	Implant/TE rupture	n (%)	1 (0,7%)	1 (0,9%)	0 (0%)	0.656
	Implant malposition	n (%)	0 (0%)	0 (0%)	0 (0%)	

P < 0.005 was considered statistically significant.

¹The total number of breasts with early postoperative complications is smaller than the frequency of the listed early postoperative complications, due to some of the breasts having multiple early postoperative complications following the surgery.

²Skin flap necrosis including both partial and total necrosis.

³Capsular contracture for Baker grade 3-4 (41).

The table includes breast implant placement for both tissue expander and permanent implant.

Abbreviations: TE, tissue expander; iv., intravenous.

Table 6: Number of breasts needing reoperations due to postoperative complications following the primary operation, during 2017-2021.

			Total n=137	2017 n=29	2018 n=19	2019 n=36	2020 n=27	2021 n=26
Reoperations	Wound revision	n (%)	9 (6,6%)	0 (0%)	3 (15,8%)	1 (2,8%)	3 (11,1%)	2 (7,7%)
	Hematoma evacuation	n (%)	8 (5,8%)	1 (3,4%)	2 (10,5%)	1 (2,8%)	0 (0%)	4 (15,4%)
	Capsulotomy¹	n (%)	15 (10,9%)	1 (3,4%)	3 (15,8%)	5 (13,9%)	3 (11,1%)	3 (11,5%)
	Implant removal with exchange to new implant or TE	n (%)	1 (0,7)	1 (3,4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Implant removal without exchange	n (%)	19 (13,9%)	1 (3,4%)	2 (10,5%)	7 (19,4%)	6 (22,2%)	3 (11,5%)

¹: Capsulotomy due to Baker grade 3-4 n=1, capsulotomy needed in secondary operation with implant exchange from tissue expander to permanent implant n=14.

Some of breast had several reoperations, since the breast developed several different postoperative complications after the primary operation.

Abbreviation: TE, tissue expander.

Table 7: Number of breasts needing additional surgery after the primary- or secondary operation to obtain an aesthetic favorable result, during 2017-2021.

			Total n=137
Additional surgery	Fat-transplantation	n (%)	31 (22,6%)
	Mastopexy	n (%)	5 (3,6%)
	Breast reduction	n (%)	7 (5%)

Appendix

Appendix 1: Baker Classification of capsular contracture (41)

Grade	Description
I	Soft.
II	Minimal, implant palpable not visible.
III	Moderate, palpable, and visible.
IV	Severe, hard, painful with distortion.

Appendix 2: Clavien-Dindo Classification of surgical complications (47)

Grade	Definition
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.
II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
III	Requiring surgical, endoscopic, or radiological intervention.
IIIa	Intervention not under general anesthesia.
IIIb	Intervention under general anesthesia.
IV	Life-threatening complication including central nervous system complications requiring intermediate care/intensive care unit management.
IVa	Single organ dysfunction including dialysis.
IVb	Multiorgan dysfunction.
V	Death of a patient.

Appendix 3: SKIN-Score for assessing severity and extent of mastectomy skin flap necrosis (MSFN) (61)

Depth of MSFN		
Score	Definition	
A	None, no evidence of MSFN.	
B	Color change of skin flap suggesting impaired perfusion or ischemic injury. May be cyanosis or erythema.	
C	Partial thickness skin flap necrosis resulting in at least epidermal sloughing.	
D	Full thickness skin flap necrosis. Areas that are not definitely full thickness should be considered partial thickness.	
Surface area of MSFN		
Score	% Area	Definition
1	0	None.
2	1-10	Breast, change affects 1-10% of breast skin. NAC, change affects 1-10% of nipple-areolar complex.
3	11-30	Breast, change affects 11-30% of breast skin. NAC, 11-30% of NAC effected, or total nipple involvement. Because the nipple itself is considered key to breast aesthetics, if there is MSFN involving the entire nipple, the surface area score of the NAC is automatically upgraded to surface area score of at least 3, even if the nipple represents < 11% of the surface area of the NAC.
4	>30	Change affects >30% of the breast skin or >30% of NAC.

Each breast is assigned both number and a letter score to characterize the severity of MSFN, based on 2 characteristics: 1 the greatest depth of MSFN and 2 the surface area involved of the area of greatest depth. In cases of nipple-sparing mastectomy, the breast mound and nipple-areolar complex (NAC) are scored separately.

Appendix 4: Proposed Definition and Grading System for Mastectomy Skin Flap Necrosis
(48)

Severity	Definition	Example
1	Necrosis requiring any deviation from normal postoperative course	Change in standard follow-up protocol, additional wound care, topical treatment
2	Necrosis requiring procedural intervention	Debridement at bedside or in procedure room
3	Necrosis requiring return to the operating room	Any skin flap necrosis managed in the operating room

