Skin Sparing Mastectomy and Immediate Reconstruction for Breast Cancer

A three to five year follow-up study of post-operative patients looking at cosmetic outcome

By

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I, Elsie Maria Muller hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Summary /Abstract:

Skin Sparing Mastectomy and Immediate reconstruction for Breast Cancer – A three to five year follow-up study of post-operative patients looking at cosmetic outcome

AIM

The aim of this study is to look at the cosmetic outcome of immediate reconstruction using either a pedicled myocutaneous flap, or an expandible breast implant by means of

- Eliciting the patient's own impression of ocsmetic outcome
- Qualitative evaluation by a panel review of standardised patient photographs
- Quantitative evaluation by means of standardised breast measurements

PATIENTS AND METHODS

Evaluation of all patients who have been treated with skin sparing mastaectomy and immediate reconstruction by means of

- Three photographs at the distance of 1 metre – neck to mid abdomen with the arms raised, at the side and a profile view. These photographs will be reviewed by an independent panel.
- Objective assessment looking at breast retraction, nipple deviation, skin atrophy, skin change (telangectasia/oedema) and scar appearance.
- Self assessment by means of an interview with the patient

END POINT

Primary end point of the study is to evaluate cosmetic outcome after reconstruction looking at the patient's self assessment, objective outcome assessment and photographic panel assessment.

Contents

Abbreviations

SSM:	Skin Sparing Mastectomy
TRAM Flap:	Transverse Rectus Abdominis Musculocutaneous Flap
DCIS:	Ductal Carcinoma in Situ
LD Flap:	Latissimus dorsi myocutaneous flap
BCS:	Breast Conservation Surgery

CHAPTER ONE: Background and Literature Review

1 Introduction

Over 100 years ago Halsted described the radical mastectomy for early breast cancer.[1] This involved wide, en bloc removal of the tumour, normal surrounding structures of the chest wall, and contents of the axilla. For 75 years this remained the treatment of choice for women with breast cancer. Most tumours could be resected using this approach and local recurrences were rare. However, this radical surgical approach was associated with significant short- and long term morbidity. Removal of the pectoralis muscles resulted in major aesthetic chest wall deformity. Other complications involved impaired range of movement, chronic lymphoedema and poor quality of life. However, the most important weakness of radical mastectomy was its failure to influence long-term survival.

A randomized prospective trial of radical mastectomy (Halsted) versus modified radical mastectomy in 311 breast cancer patients was done by Maddox et al between 1975 and 1978.[2] After a median follow-up of 5.5 years, there was no significant difference in disease-free survival or in overall survival between the two groups. There was a trend toward improved 5-year survival rates in the radical mastectomy group compared to the modified radical mastectomy group (84% vs. 76%, $p = 0.14$). There was also an increased incidence of local wound recurrence in those patients receiving modified radical mastectomy, but the differences were not statistically significant ($p = 0.09$).The added superior functional and cosmetic benefit of modified radical mastectomy resulted in this becoming the standard operation for all women with operable breast cancer.[3]

Subsequently the migration toward less radical surgery has resulted in breast conservation as an option in woman with breast cancer. It is now well established that wide local excision with axillary lymph node dissection plus irradation is as effective as modified radical mastectomy for patients with early breast cancer.[4] The rationale for this conservative approach is the realisation that breast cancer is a systemic disease from the time of diagnosis.

Immediate breast reconstruction after mastectomy has increased over the last decade following the demonstration of its oncological safety and the availability of reliable methods of reconstruction. Immediate breast reconstruction can be achieved with a variety of autogenous tissue techniques or prosthetic devices. The operation deliberately sets out to preserve as much of the original breast skin cover as possible and reconstruction takes place at the same time. Despite reports claiming excellent cosmetic results with this technique, little objective evidence exists supporting this. In this study patients who had undergone skin sparing mastectomy (SSM) and immediate reconstruction were recalled to evaluate cosmetic result and patient satisfaction three to five years after the procedure.

2 Options in breast cancer surgery

A patient diagnosed with breast cancer has different surgical options. Numerous studies exist, comparing the outcomes after breast-conserving surgery (BCS), breast reconstruction and mastectomy.[5-6] In a twenty-year follow-up of a randomized study comparing breast-conservation and radical mastectomy,[7] the incidence of local recurrence in the breast conservation group was higher than in the radical mastectomy group ($p<0.001$). However, the long-term survival rate 20 years after the surgery among women who underwent BCS was the same as women who underwent radical mastectomy ($p=1$). Although BCS is an excellent treatment for breast cancer in appropriately selected patients, many patients will undergo mastectomy because of personal preference, inability to obtain control of the margins with lumpectomy or because of the inability to receive postoperative breast irradiation. Lumpectomy's followed by irradiation in women with relatively small breasts or inner-quadrant tumours can result in substantial postlumpectomy deformity and assymmetry, and therefore mastectomy may be preferred in these patients as well. Consideration of breast reconstruction in these patients before their definitive operations can be an excellent adjunct to their breast cancer management.

3 Skin Sparing Mastectomy

3.1 What is a skin sparing mastectomy?

In skin sparing mastectomy, the skin incision is planned to preserve the normal skin envelope of the breast. The skin flaps are elevated at the subcutaneous level to expose the entire gland which is then excised as in a standard mastectomy and delivered through this keyhole approach. Any lymph node dissection is then performed through this excision or through a separate incision in the axilla.

There are several benefits associated with preserving the skin. First, the skin colour and texture will match the contralateral breast. Second, ptosis is more easily achieved. Third, symmetry of the breast is optimized, and there is preservation of the natural cleavage appearance of the breast, while fourth retention of the inframammary fold will facilitate the position of the implant or flap on the chest wall. Finally, preserving the skin also results in retention of some sensation in the breast.

The main disadvantage of a skin sparing mastectomy is the technical difficulty thereof. It has a prolonged operating time compared to normal mastectomy. In addition it requires patience and expertise on the part of the surgical oncologist. An ablative and reconstructive surgeon should be available at the same time, which might result in difficult logistics. Because of the complex nature of this surgery, it requires much advanced planning.

3.2 Is skin sparing mastectomy safe?

There are no randomized controlled trials comparing skin sparing mastectomy and reconstruction against simple mastectomy. However, it is argued that local recurrence is dependant on factors other than simple tumour clearance or the extent of skin excised during mastectomy. The evidence would suggest that local recurrence usually heralds systemic disease, and is predominantly a reflection of biological tumour behaviour.

Since the introduction of SSM in 1991, concerns on local control and recurrence rates have been extensively discussed in the literature [8,9] A recent study examined the incidence of local recurrence in a consecutive series of breast cancer patients had undergone SSM and immediate breast reconstruction (IBR) at a single population-based institution over a 15 year period.[9] All of the local and regional recurrences were handled by salvage surgery followed by adjuvant oncological therapies. During a mean follow-up of 35 months after the detection and treatment of the locoregional recurrences none of the patients developed new recurrences. In another study from Germany, [10] several factors were associated with local recurrence and included tumor size, poor tumor differentiation, and positive node involvement. Therefore, in a correctly selected patient, SSM followed by IBR seems to be an oncologically sound procedure. Generally the recurrence rate in patients with stage 1 and 2 breast cancer, is between 4% and 7%.[11]

3.3 Patient selection for Skin Sparing Mastectomy.

3.3.1 Tumour-related factors

The tumour-related factors which influence the outcome after SSM and reconstruction are mostly related to the size and location of the tumour. Tumours smaller than 5cm in diameter which are centrally located are ideal. Retro-areolar tumours or tumours which are deeper in the breast tissue are technically easier to remove. In addition, patients receiving a prophylactic mastectomy for a genetic mutation which increases their risk for breast cancer significantly, are excellent candidates for SSM and immediate reconstruction. Patients receiving a mastectomy for ductal carcinoma in situ (DCIS) are also good candidates. Peripherally situated tumours (especially inner quadrant/ inframammary fold) are more difficult to treat with skin sparing mastectomy as the tumour is much closer to the skin which needs to be preserved. Skin involvement obviously precludes a patient from having a SSM.

The use of peri- and post-operative radiotherapy also impacts on the feasibility of SSM. Irradiation severely impair the wound healing process, and permanently damages soft tissue. Even within the first few weeks or days after radiotherapy, tissue

edema, imflammation and desquamation might be visible.[12] Delayed radiation effects might occur several months or years after the treatment with fibrosis and atrophy, and the replacement of adipose tissue with collagen.[13]

With sentinel lymph node sampling we are now able to predict with a high degree of accuracy which patients have lymph node involvement. To a large extent it will be this group of patients who have involved lymp nodes who will need post-operative radiotherapy. In this patient group, delayed reconstruction might be a better option.

Table 1.1: Summary of Patient selection for Mastectomy and Immediate Breast Reconstruction: Tumour-related factors

Indications:

- Small tumours
- Centrally located tumours / retro areolar
- DCIS
- Prophylactic mastectomy

Contraindications:

- Relative:
  - Peripherally located
  - Locally advanced breast cancer
- Absolute:
  - Advanced breast cancer
  - Post operative radiotherapy

3.3.2 Patient-related factors

The complication rates for immediate breast reconstruction in patients with major co-morbidities are significant.[14] Therefore smoking, obesity and the presence of major co-morbidities have traditionally resulted in these patients not being offered breast reconstruction for breast cancer. Smoking is a problem because of diseased vessels and atherosclerosis in the area of the flap, increasing the risk of flap necrosis. Any

vascular disease or diabetes might cause small vessel atherosclerosis which will influence the success of the procedure.

Risk factors for a prolonged anaesthetic might also be a consideration. In patients with severe cardiopulmonary problems, chronic obstructive airway disease or uncontrolled hypertension, a shorter and less complicated procedure might be of benefit.

Another important patient related factor is the size of the breasts. Large breasts are difficult to reconstruct. In these patients the procedure might also include a reduction mammoplasty on the contralateral side. Furthermore, if the patient is overweight, the cosmetic outcome might not be as good as in a smaller patient. In such a patient a procedure involving the abdominal wall muscles might not be possible.

A recent study attempted to identify risk factors which resulted in increased complications after combined skin sparing mastectomy and immediate prosthetic reconstruction.[15] Mild complications occurred significantly more often in patients who were older than the mean age of 43 years, in breasts that were more than average sized, and if the surgery was performed by a fellow in oncologic surgery. Similarly, implants were lost significantly more often in patients who were obese, patients who smoked, and in breasts that were more than average-sized. Their study'sconclusion was that the clinically relevant increase of risk of implant loss should lead to reluctance to perform combined skin sparing mastectomy and immediate prosthetic breast reconstruction in obese patients who smoke (32% loss), and in those with more than average sized breasts (27% loss).

3.4 Technical aspects of the skin sparing mastectomy

3.4.1 Skin incision

Skin-sparing mastectomy can be classified by the type of incision used and the amount of skin removed (see Figure 1.1). Type I SSM is commonly used for prophylactic purposes and for patients with cancer diagnosed with a pre-operative

needle biopsy. Lateral extension of the incision may be necessary to improve exposure to the axillary tail. Type II SSM can be used when the superficial tumor or previous biopsy is in proximity to the areola. Type III SSM can be used used when the superficial tumor or previous incision is remote from the areola. Type IV SSM is used in large, ptotic breasts when a reduction is planned on the opposite breast.The skin incision should be carefully planned and marked in consultation with a plastic surgeon. The inframammary fold is delineated with a marking pen pre-operatively. This should be done with the patient in an upright position. The nipple-areola complex and skin overlying superficial tumours should be removed in continuity with the mastectomy specimen.[42]

Figure 1.1: Types of incisions used in SSM

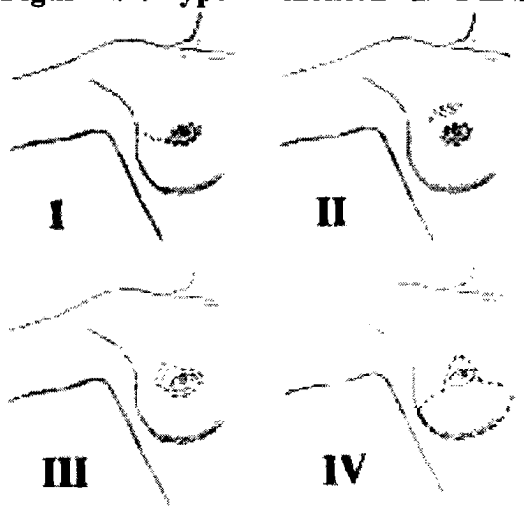


Table 1.2: Summary of incisions used for different types of SSM

Type	Classification
I	Only nipple-areola removed
II	Nipple-areola, skin overlying superfiscial tumours and previous biopsy incision removed in continuity with nipple-areola
III	Nipple-areola removed, skin overlying superfiscial tumours and previous biopsy incision removed without intervening skin
IV	Nipple-areola removed with an inverted or reduaction pattern skin incision

3.4.2 Extent of dissection

The skin flaps are elevated superficial to the enveloping fascia of the breast. This anatomical plane should be relatively avascular if developed correctly. The subcutaneous vascular plexus has to be preserved to avoid skin flap necrosis. The use of monopolar diathermy should be avoided as much as possible to avoid compromising the skin flap.

The dissection continues in a centripetal fashion until the pectoralis fascia is encountered. The anatomical boundaries are the same as for a simple mastectomy. The inframammary ridge should always be preserved. This occurs at the inferior margin of the pectoralis major muscle at the 6th or 7th rib. Its presence greatly facilitates the position of the prosthesis or flap within the retained skin envelope on the chest wall and is therefore a major contributor to the cosmetic success of the procedure.

4 Breast Reconstruction after the SSM

4.1 Timing of reconstruction

Breast reconstruction can be done "immediately". This is defined as reconstruction that starts at the same sime as the mastectomy. This is an excellent option for patients with early breast cancer (stage 1 or 2) and also for Ductal Carcinoma in Situ (DCIS). The advantages are many. Patients who receive an immediate reconstruction have better body image, self-esteem and satisfaction than women who have delayed reconstruction.[16] The skin envelope is preserved and this has the advantage that aesthetic results are generally better.[17] In addition, the overall cost is less because there are fewer operations and anaesthetics.[18] Disadvantages include the fact that further treatment could be delayed if there are complications such as wound infections. Another problem might be presence of residual disease or close surgical margins which may necessitate the use of post-operative radiation therapy, which can adversely affect the reconstruction.

Delayed reconstruction, defined as a reconstructive procedure which is done after mastectomy, can be undertaken at any time after the wound has healed and adjuvant therapy has been completed. Post irradiation skin changes should have stabilized, and the haematological effects of chemotherapy should have normalized before reconstruction is begun. Although delayed reconstruction is normally associated with fewer complications compared to immediate reconstruction,[14] the overall treatment is prolonged, and the cosmetic result is poorer because the skin envelope is not preserved.

4.2 The options for Reconstruction

There are several options available for breast reconstruction after mastectomy. This include the use of prosthetic implants, the use of autologous tissue flaps, or a combination of the two.

4.2.1 Prosthetic Material placed Posterior to Pectoralis Major

- Simple breast implant
- Tissue expander followed by an implant (immediate delayed reconstruction)
- Permanent expander-implant
- Adjustable prosthesis

4.2.2 De-epithelialised Autologous Tissue Flaps

- Latissimus dorsi myocutaneous flap (LD)
- Transverse rectus abdominus myocutaneous flap (TRAM)
- Inferior and superior gluteal flaps
- Lateral transverse thigh flap

4.2.3 Combination of Prosthetic Material and Autogenous Tissue

- Combination of a LD flap with a tissue-expander or implant

4.3 Prosthetic Reconstruction options

Breast implants were first described in 1895 to try and augment the size or shape of women's breasts. The earliest known implant was attempted by Czerny, using a woman's own adipose tissue.[19] Various synthetics were used throughout the 1950's and 1960's, including silicone injections. Development of silicone granulomas and hardening of the breasts were in some cases so severe that women needed to have mastectomies for treatment.[20]

Today different type of implants are on the market. Saline-filled breast implants have an outer shell of silicone elastomer. The implant is generally filled with salt water after it had been placed in the body. Saline-filled implants are the most common implant used in the United States due to restrictions on Silicone implants, but are rarely used in other countries. Good to excellent results may be obtained, but as compared to silicone gel implants, saline implants are more likely to cause cosmetic problems such as rippling, wrinkling, and be noticeble to the eye or the touch.[21]

Fourth and fifth generation silicone implants are on the market today. They contain a gel filler which reduces potential leakage of the silicone compared to earlier devices. A variety of both round and tapered anatomic shapes are available. Anatomic shaped implants are uniformly textured to reduce rotation, while round devices are available in smooth or tectured surfaces. Studies of these devices have shown significant potential improvements in safety and efficacy over the older implants with low rates of capsular contracture and rupture.[22-23]

Reconstruction with implants is easier than reconstruction with autologous tissues, requiring less training and experience from the surgeon. The procedure is quicker and is less invasive. It is ideal for the older patient (over 65 years) and for patients who are not in a good physical condition.[24]

4.3.1 Implant reconstruction

A textured or smooth breast implant is used directly under the mastectomy flap. Subcutaneous implantation is associated with a high incidence of flap necrosis, wound dehiscence, implant extrusion, infection and peri-implant capsular contracture.[25] Capsular contracture is a common complication and numerous randomized controlled trials addressing the efficacy of textured surface breast implants in reducing capsular contracture have yielded equivocal results. In a recent meta-analysis which included eleven trials, only three of these studies demonstrated significantly lower rates of capsular contracture with the use of textured implants.[26] However, when the data was collated, a protective effect for surface texturing on the rate of capsular contracture was demonstrated.

The first indication for insertion of an implant is in the patient where the volume requirement is small and there is adequate soft tissue coverage. A permanent implant can be placed straight away.

Second, implants can be used as a temporary measures while waiting for skin to expand or for radiotherapy to finish. Usually there is enough skin remaining on the chest wall in order for reconstruction to be achieved by simply inserting an implant. In most cases, however, extra skin needs to be created by stretching the available remaining skin. These patients are fitted with a temporary implant which will then be removed at the time of definite reconstruction.

Third, prosthetic material is often used to aid a LD flap. In this technique a flap of skin and muscle is taken from the back and transferred to the front of the chest where it is used to cover an implant.

4.3.2 Two stage Expander-implant reconstruction (Immediate expander combined with delayed prosthesis reconstruction)

The expander-implant reconstruction involves the submuscular placement of an inflatable silicone balloon. This balloon is subsequently expanded by a series of

post-operative saline injections through a remote port. A breast mound of desirable dimensions is created after several weeks. The temporary expander is removed after 4 to 6 months and replaced by a permanent implant.

The advantage of this technique is the fact that in the long term, local tissue will form the reconstructed breast. This tissue is similar in colour and texture to the opposite breast. Historically, delayed placement of the tissue expander was preferred in an attempt to decrease local complications before the reconstruction was done. However, immediate tissue expander reconstruction after mastectomy is now well established. [27-28]

Following placement of the expander in the submuscular pocket at the time of mastectomy, expansion is carried to tissue tolerance (generally 50% of the expander volume). In the absence of necrosis or infection, post-operative expansions generally start 10 to 14 days after surgery. The volume at which the breast mound looks equal to the contralateral breast is noted (to guide the choice of size of the permanent implant). The expander is then overinflated to about 120% of the desired final breast volume. Subsequent volume reduction results in a more naturally-shaped breast (looser skin envelope) and a greater potential for ptosis.[29]

Although completion of expansion usually takes 6-8 weeks, expander-to-implant exchange is usually delayed for some months after achieving the desired size. This delay may not be necessary as there is probably no differences in adverse capsular contracture rates between rapid and slow expansion of the breast, or timing of the implant reconstruction. [29-30] In a study done by single surgeon on 1221 patients, the exchange for a permanent implant was perfomed as early as 6 weeks after completion of expansion. The overall incidence of perioperative complications for both the insertion and exchange procedures was 5,8%.[29] The most common perioperative complication was infection (2,5%). In addition, there was no difference in complications in those who were expanded during chemotherapy or not (p=0.199).

Few reports have critically evaluated long-term outcomes following two-stage implant reconstruction. In a review of tissue/expander breast reconstructions performed by a single surgeon (315 patients) one to three years after mastectomy over

a twelve-year period, 88% of all tissue expander/implant reconstructions had an overall aesthetic result graded as good, very good or excellent.[31] Non-irradiated patients had a better overall aesthetic result than patients who received post surgery radiotherapy ($p<0,001$). The author reported that irradiation remained the most significant predictor of overall aesthetic result rather than body mass index or pre-operative breast size. The incidence of capsular contracture was reported as 10% in non-irradiated patients compared to 20% in previously irradiated implants.

4.4 Autogenous tissue reconstruction

Immediate reconstruction using autologous tissue yields the most durable and natural-appearing results with the greatest consistency. It solves the problem of capsular contracture because the breast volume is replaced by the patient's own tissue. No prosthesis is required, obviating problems such as infection, extrusion, malposition and capsular contracture.[32]

It offers unrivalled versatility, including creation of excellent ptosis and fill of the infraclavicular hollow and anterior axillary fold. These tissues can withstand post-operative radiotherapy and can also be used in previously irradiated patients undergoing completion mastectomy for recurrence. The excellent vascularity of the tissues leads to improved wound healing.[33]

The autogenous tissues available in decreasing order of frequency of use are the TRAM (Transverse Rectus Abdominis Myocutaneous), LD (Lattissimus Dorsi), Superior Gluteal, Inferior Gluteal, Lateral Transverse Thigh and Taylor-Rubens Peri-iliac flaps.

4.4.1 TRAM flap

This is the "gold standard" of breast reconstruction, in part because of greater patient satisfaction with these techniques[34-35]. It looks natural and has a natural feel. In the correctly selected patient, there are few complications and excellent donor site cosmesis.

Because a large volume well vascularised autogenous tissue is used for the reconstruction, it can withstand post-operative radiotherapy better than any other reconstruction. It could potentially be used in a site with previous irradiation or a tight chest wall skin. Good ptosis is usually achieved with the advantage of concomitant reduction of excess abdominal tissue.[34]

This is not a short procedure and therefore it is not suitable for a patient who is generally unfit for a major operation. It is not used in the elderly or in patients with a lack of adequate abdominal tissue because of previous irradiation or surgery. Generally, patients selected for this procedure should not have any increased risk for vascular complications: smokers and diabetic patients have the increased risk of complications because of atherosclerosis and small vessel disease.[36-37] Obesity is also a contra-indication: it is well documented that complications are directly associated with a higher body mass index.[14.38] The risk of post-operative partial or total flap loss and bleeding should be discussed with the patient. The general incidence of haematomas is 4%.[36] Other complications include infection (12%), umbilical necrosis, partial flap loss (16%) and total flap loss (1%).[24] The abdominal wall might be damaged or weakened to the point where the patient might develop an abdominal wall hernia or bulge. This could potentially be corrected with a mesh over the abdominal wall. [14.36]

(a) Pedicled TRAM flaps

A wide ellipse of skin and fatty tissue is removed from the patient's lower abdomen, but left attached to the low rectus abdominis muscles. A tunnel is created between the abdominal dissection and the defect left by the removal of the breast and the flap is passed up onto the chest wall. The flap gets its blood supply from the superior epigastric artery and vein, which remain attached to the flap in order to keep it alive. The flap is then shaped to form a facsimile of the breast.

(b) Delayed pedicled TRAM flaps

One way to improve the blood supply to the TRAM flap is to perform a delay procedure one week before the actual reconstruction. In the delay procedure the inferior vessels are divided, encouraging the superior vessels to become larger and reducing the risk of vascular insufficiency to the flap.

(c) Free TRAM flaps

The inferior epigastric vessels are divided and then reattached micro-surgically to the recipient vessels in the chest wall or axilla. The advantage of doing this is that the blood supply is more direct and less likely to cause partial flap loss or fat necrosis. Only a small part of the rectus abdominus muscle is sacrificed for this procedure and there is less post-operative pain and abdominal wall weakness. Aesthetic outcome is good because of excellent blood supply that allows more aggressive shaping of the flap. The disadvantage of the free flap is the fact that there is total dependence on the success of the anastomosis of the blood vessels to maintain viability of the flap. If the anastomosis obstructs, there will be a high failure rate.[14]

(d) Deep Inferior Epigastric Perforator (DIEP) Flap

A relatively new variation of the TRAM flap is the deep inferior epigastric perforator flap. In this flap the skin and fat island are identical to that of the TRAM flap but one, two or three perforating blood vessels are dissected through the rectus abdominis muscle so that the muscle can be left in the abdomen rather than harvested with the flap. The DIEP flap consists only of skin, fat and blood vessels. No muscle is sacrificed. Fat necrosis and partial flap loss can occasionaly be a problem.[39-40]

4.4.2 Latissimus Dorsi / Myocutaneous flap

Another reliable way of reconstructing the breast is the latissimus dorsi muscle and skin flap. It is a a very effective reconstructive method where there is skin insufficiency after the mastectomy. It is also used for the patient who has insufficient lower abdominal tissue or who is medically unfit for a TRAM flap. It can successfully be used in a patient who had a previous abdominoplasty or a previous TRAM flap for a contralateral breast cancer. Salvaging partial TRAM flap necrosis in a patient with a distorted, reconstructed breast can be done with a latissimus dorsi flap.[24]

The anatomy of the latissimus dorsi muscle is predictable and can be transposed to the anterior chest wall in the standard way or by reversing the arc of rotation. A skin island can be harvested with the muscle and this can be used together with the length and bulk of the muscle to cover the defective area. The dominant vessel is the thoracodorsal artery (off the subcapsular artery). This flap can be transferred either on its pedicle or as a free tissue microsurgical transfer.[24]

Most plastic surgeons believe that a better aesthetic result is obtained by first using a tissue expander under the flap and then replacing it with a permanent implant. Unfortunately the patient is left with a significant donor site scar and the risk of a donor site haematoma, seroma or infection.[32]

4.3 Nipple and Areolar Reconstruction

This is usually performed after the breast shaping has been completed, typically 6-8 weeks after the reconstruction. The most important factor of nipple reconstruction is its location. Even slight malpositioning can give an unnatural appearance to an otherwise properly reconstructed breast.[24]

Techniques for nipple recreation include a simple local flap of skin and fat to create a projecting nub, tattooing to pigmentate the nipple and create the areola, or a full

thickness skin graft.[41] Nipple projection decreases postoperatively, requiring a 50% overcorrection at the time of surgery.

Nipple-areola preservation is a logical step in the even more conservative management of breast cancer. Initial concerns regarding its oncological safety was expressed by numerous authors.[42.43.44] A retrospective review of 217 patients was performed by Simmons et al and published in 2003.[45] The aim of this study was to determine frequency of malignant involvement in the nipple areola complex. Overall, 10,6% of resected nipples harbored malignancy. Even in a subgroup of patients with most favorable cancers, the nipple involvement was 6,7%. Where the areola was evaluated separately from the nipple, the incidence of cancer was only 0,9%.[45]

However, recently more and more authors are feeling that nipple-areola preservation is the logical step in the ever increasing conservative management of breast cancer. Low local recurrence rates have now been reported by numerous studies. [46.47.48] Evaluating the outcome of different techniques of reconstruction following nipple-areola-preserving envelope mastectomy with immediate reconstruction,[49] the authors found that the envelope mastectomy with nipple preservation and immediate reconstruction has improved cosmetic outcome and low local recurrence rates.

4.4 Cosmetic Outcome

There are few reports in the literature comparing the results of various methods of breast reconstruction. The evaluation of breast reconstruction is ill defined and has received little attention.[50] McCraw and coworkers[51] found a higher complication rate and lower patient satisfaction after prosthetic inplants than after TRAM flap reconsruction. Rosen and collegues[52] found that the complication rates were similar between the two methods, but the aesthetic outcomes were felt to be better after TRAM flap reconstruction. Kroll and Baldwin[53] compared the aesthetic results in 325 postmastectomy reconstructions and found that the aethetic resluts were similar for TRAM flap, LD flap and tissue expansion, but that tissue expansion was less successful in obese patients. Hidalgo[54] reviewed 26 cases of SSM with immediate

TRAM flap reconstruction and reported excellent to good results in 75% of the patients.

CHAPTER TWO: Patients and Methods

All cases of SSM and immediate reconstruction performed from 1 January 1998 to 31 December 2001, were reviewed. A total of 54 patients underwent SSM and immediate reconstruction during the study period.

1 Aim

The aim of this study is to look at the cosmetic outcome of immediate reconstruction using either a pedicled myocutaneous flap, or an expandible breast implant at Groote Schuur Hospital. The patients were reveiwed 3 to 5 years after their surgery.

2 Inclusion Criteria

1. SSM and immediate reconstruction performed between 1 January 1998 and 31 December 2001.
2. Contact details made available to the investigator and willingness to return for a follow-up visit between 18 and 31 March 2004.
3. Willingness to consent and participate in the follow-up study.

A shortcoming of the current study is the fact that only 22 of the 54 patients could be followed up. The reasons for no follow-up is summarised in Table 2.1.

Table 2.1: Reasons for no follow-up

No of patients	Reason for no follow-up
15	Telephone numbers not in use anymore
7	Telephone numbers not available in notes
5	Distance from hospital
2	Died
3	Did not attend

3 Aesthetic Evaluation

Numerous methods have been used in previous studies evaluating cosmetic results after breast reconstruction. [55,56,57,58] Developing objective, quantifiable methods to assess breast appearance is important to make conclusions about cosmetic results. A few measures of aesthetic properties such as symmetry, atrophy, skin changes and scar assessment have been used in the past.[59] In most of these assessments the localization of the nipple complex is the most widely-used aesthetic measure. [56,59]

The aesthetic evaluation in this study were based on a photographic assessment, an objective assessment and a patient self assessment.

3.1 Photographic Assesment

Each patient was photographed from a distance of 1 meter. Three photographs were taken: (1) to include neck to mid abdomen from a frontal view with the arms raised, (2) with the arms at the side and (3) a profile view from the treatment side with the arms raised. These were reviewed by an independent panel consisting of five members including one surgeon, one general practitioner, one nurse, one house officer and one member of the public. The panel members were ignorant of the procedure performed and a cosmetic score was calculated for each patient using a four point score. The method used was to compare the reconstructed breast to the normal breast. (Table 2.2). This method effectively assesses the contour of the breast, symmetry of shape and volume, position of the lower edge of the breast, as well as symmetry, size and colour of the nipple-areola complex.[59] The degree of visibilty of the scars was assessed by the investigator as part of the objective assessment.

Table 2.2: Scoring system for photographic panel

	Score	Definition
Excellent	4	No visible difference between the breasts
Good	3	Slight difference
Fair	2	Obvious difference – no distortion
Poor	1	Distortion

3.2 Objective assessment

Parameters evaluated were breast retraction, nipple deviation, atrophy of the breast, skin changes and an assessment of the scar.

- ***Breast Retraction[58]***

The *Breast Retraction Assessment* quantifies the symmetry of nipple locations. The nipple complexes are localized and from these measurements the *Breast Retraction Assessment* is done. The *Breast Retraction Assessment* quantifies the symmetry of nipple locations.

In order to measure breast retraction a clear acrylic sheet supported vertically and marked as a grid at 1 cm intervals was employed. The Y-axis was used as a midline and the X-axis at the top of the grid. X values increased from midline laterally in both directions so that all the values were positive. Y-values increased positively in an inferior direction. The patient stood behind the grid, facing it so that the jugular notch and xyphoid were centered to the Y-axis at the midline. The observer then located the x- and y- coordinates for the nipple of each breast. Breast Retraction (BR) values were then calculated by employing the Pythagorean theorem:

$$BR = \sqrt{(Xr - Xl)^2 + (Yr - Yl)^2}$$

This value showed the amount of retraction of the treated breast by comparing it to the untreated breast. For this study Breast Retraction was determined for each patient with the arms at the patient's side.

- ***Nipple Deviation***

Nipple deviation was determined by comparing four measurements with each other: the distance between the nipple and the clavicle measured in a straight line from the nipple upwards; the distance between the nipple and the inframammary fold; the distance from the nipple to the anterior axillary line and the distance to the midline over the sternum. The reconstructed side was then compared to the normal side by calculating the percentage deviation. This method had been used for cosmetic assessments by other authors.[60]

- ***Atrophy of the Breast***

Atrophy of the breast was assessed by the investigator only and classified as nil, slight or severe. This is one of the main reasons why breast shape would not appear symmetrical and would influence cosmetic outcome.[59]

- ***Skin Changes***

Skin changes were assessed by the investigator only and classified as nil, slight or severe. Four different skin changes were assessed: telangiectasis, change of skin colour, pigmentation and fibrosis.

- ***Scar Assessment***

The scar was assessed by the investigator as not visible, slight or distorted and hypertrophied.

At the end the objective assessment was summarized as in Table 2.3.

Table 2.3: Scoring system for objective assessment

	Score 2	Score 1	Score 0
Breast Retraction Assessment (cm)	<3.1	3.1-6.5	>6.5
Nipple deviation (%)	<5	5-10	>10
Atrophy	nil	Slight	Severe
Skin change	nil	Slight	Severe
Scar	Not visible	Slight	Distorted/hypertrophic

3.3 Patient Self Assessment

Patients were asked about their own assessment of the cosmetic outcome of the procedure. They were given the opportunity to score their own cosmetic results on a scale of 1 to 4 as in Table 2.4.

Table 2.4: Scoring system for patient self-satisfaction

Satisfaction	Score
Very satisfied	4
Moderately satisfied	3
Slightly satisfied	2
Not at all satisfied	1

Patients were asked whether they would recommend this procedure to other patients and they had the option to answer yes, no or unsure.

4 Statistical Analysis

The problem with this study is the small sample size and the fact that only 23 of the 54 patients who had this procedure could be followed up. Because of this small

sample size, the study has low statistical power, making it difficult to detect a difference as significant even if there is a real difference in the population. The nonparametric Mann-Whitney test was used to test differences between the groups and the reason this was chosen over the t test is due to the small sample size. For the above named reason descriptive statistics are presented using means with standard deviations or numbers with percentages.

CHAPTER THREE: Results

1 Follow-up

Of the 54 patients who underwent SSM and immediate reconstruction between 1 January 1998 and 31 December 2001, 22 were followed up between 18 and 31 March 2004 (40%). The reasons for not following up are illustrated in Table 3.1.

Table 3.1: Reasons for no follow-up

Nr of patients	Reason for no follow-up
17	Telephone numbers not available in notes
5	Telephone numbers not in use anymore
5	Lives far away
2	Died
3	Did not attend

2 Reconstructive Methods and Contralateral Breast Management

The procedure distribution in the 54 patients who underwent SSM and immediate reconstruction between 1 January 1998 and 31 December 2001 is illustrated in Table 3.2.

Table 3.2: Reconstruction type in 54 patients who had SSM and IR between 1998 and 2001

Amount of patients	Reconstruction type
25 (46%)	TRAM
14 (26%)	LD
15 (28%)	Prosthesis

Three reconstructive methods were used on the 22 patients who were followed: TRAM flap, LD flap or Prosthetic implantation. Table 3.3 illustrates the breakdown of patients in each group.

Table 3.3: Reconstruction type in 22 patients who were followed up

Amount of patients	Reconstruction type
14 (63%)	TRAM
2 (9%)	LD
6 (27%)	Prosthesis

Twelve of the patients in the follow-up group (10 of the TRAM flap patients and 2 of the prosthetic reconstruction patients) had a procedure on the opposite side to improve the cosmetic result. In all cases this was a reduction mammplasty.

3 Age

The mean patient age was 50.2 years (age range 36 – 62 years). The mean patient age by reconstructive method was the following:

1. TRAM flap: 50.4 years
2. LD flap: 48.5 years.
3. Prosthetic reconstruction: 50.2 years

4 Systemic risk factors at the time of surgery

The risk factors obtained retrospectively from the patient folders entailed the following: a history of smoking at the time of surgery; ischaemic heart disease defined as a history of a myocardial infarction or angina; anti-hypertensive treatment; diabetes mellitus and chronic obstructive pulmonary disease. These results are summarised in Table 3.4. In 4 of the patients more than one risk factor were present. Two of these 4 high risk patients received TRAM flaps, one a LD flap and one a prosthetic reconstruction.

Table 3.4 : Risk factors present at the time of reconstructive surgery

Nr of patients	Risk factor
10	None
5	Smoked tobacco at the time of operation
3	Ischaemic heart disease
7	Hypertension
2	Chronic obstructive pulmonary disease
1	Diabetes

5 Body Surface Area/ Body Mass Index

The body surface area of each patient was calculated using the height and weight of the patient during the follow-up visit. The height and weight at the time of the surgery was not always available in the patients' notes. The body surface area ranged between 1.6 and 2.1 for this group with a mean body surface area of 1.83.

Body Mass Index = kg/m^2 (weight in kilogram divided by height in metres squared) was calculated for each patient. A Body Mass Index between 25 and 29.9 was classified as "overweight", and greater than or equal to 30, as "obese", according to the definition is used by the World Health Organization (WHO) as its international standard.

In the current study, most of the patients were overweight / obese according to body mass index. Only 5 patients had a body mass index in the normal range (22-25), 4 patients had a body mass index between 25 and 29.9 (overweight) and the other 13 had a body mass index in the obese range (>30).

6 Oncological data

The indications for surgery were ductal carcinoma in 19 of the follow-up cases and Ductal Carcinoma In Situ (DCIS) in 3 cases. All three the cases with DCIS had TRAM flap reconstructions.

Of the 19 patients with ductal carcinoma, 5 patients had tumours smaller than 2cm, 12 patients had tumours between 2cm and 4cm and 2 cases had tumours between 4cm and 5cm. The size of the tumours in each reconstructive group is summarized in Table 3.5.

Table 3.5: Type of tumour in each reconstructive group

Ductal Carcinoma	TRAM	LD	Prosthesis
Tumour < 2 cm	1	1	3
Tumour 2 - 4 cm	8	1	3
Tumour 4 - 5 cm	2	0	0

7 Post-operative Radio- ,Chemo- and Hormonal Therapy

In the ductal carcinoma group 15 had positive axillary lymph nodes on histology. Six of these 15 patients received post-operative radiotherapy for nodal involvement. Another 2 patients received post-operative radiotherapy for close margins on histology as well as positive nodes.

As summarised in Table 3.6, 3 patients who received a prosthetic implant required post-operative radiotherapy. Both the patients who received a LD flap and 3 of the patients who received a TRAM flap required radiotherapy.

Table 3.6: Type of tumour in each reconstructive group

	TRAM	LD	Prosthesis
Radiotherapy	3	2	3
Chemotherapy	10	2	4
Hormonal Therapy	11	2	6

Adjuvant chemotherapy was given to 16 of the 22 patients. Types of chemotherapy included cyclophosphamide, methotrexate and 5-fluorouracil (N=13) and cyclophosphamide, doxorubicin and 5-fluorouracil (N=3).

In the group of 22 patients, only the 3 patients with DCIS were not on adjuvant hormonal therapy (Tamoxifen) post-operatively.

8 Reconstructive data

Reconstructive methods included 14 TRAM flaps, 2 LD flaps and 6 Prosthetic implants. Twelve patients received procedures on the opposite breast to achieve symmetry. Remedial surgery was always reduction mammoplasty.

The group of patients with TRAM flaps consisted of 14 patients. Ten of them had remedial surgery on the opposite side (70%). In the LD flap group there were only 2 patients and both had remedial surgery in the opposite breast. In the group of patients who received a prosthesis, only 2 of the 6 patients had remedial surgery on the opposite side (33%). These results are illustrated in Table 3.7.

Table 3.7: Patients needing remedial surgery in the opposite breast in each reconstructive group

	TRAM	LD	Prosthesis
Reduction mammoplasty	10	2	2

9 Cosmetic Outcome

9.1 Photographic Assessment

In the group of 22 patients 5 patients scored an average of 1 (gross distortion between breasts), 6 patients an average of 2 (obvious difference, but no distortion between breasts) and 11 patients an average of 3 (slight difference between breasts). No patient scored 4 (no visible difference between the breasts).

Patients in the TRAM flap group had the best outcome. Eight of the 14 patients scored 3 points (slight difference between breasts), 4 scored 2 points (obvious difference between breasts) and 2 scored 1 point (gross distortion between breasts). In the LD flap group one patient scored 3 (slight difference between breasts) and one patient scored 2 points (obvious difference between breasts). Patients who had prosthetic implants had the worse outcome. In this group 2 patients scored 3 points (slight difference between breasts), 1 patient 2 points (obvious difference between breasts) and 3 patients only 1 point (gross distortion between breasts). Examples of patient photographs are found in Appendix A.

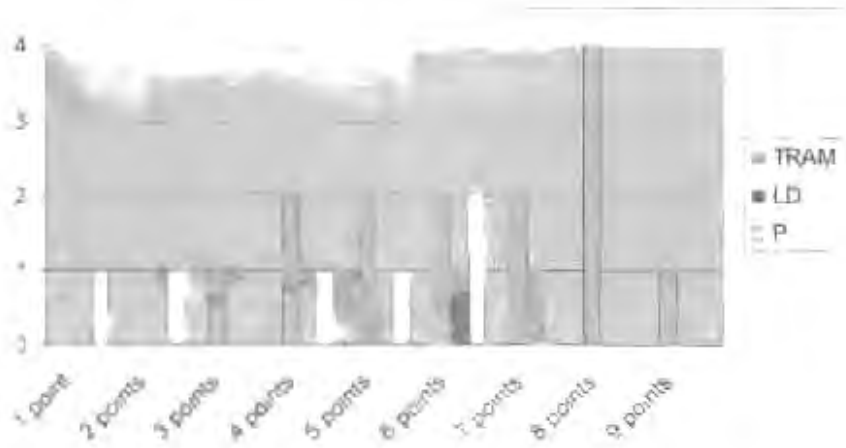
9.2 Objective Assessment

Data of each patient was collected and a total score out of a possible 10 was calculated according to Table 2.3 (page 22). The score ranged between 1 and 9. In the TRAM flap group 1 patient scored 9, 4 patients scored 8, 2 patients scored 7, 6, 5 and 4 respectively and 1 patient scored 3. In the LD flap group 1 patient scored 6 and the other 7. In the prosthesis group, 1 patient scored 1, 2, 4 and 5 each and 2 patients scored 6.

The results for the different reconstructive methods are summarized in Figure 3.1.

Figure 3.1: Objective scoring in the different reconstructive methods

TRAM = transverse rectus abdominis musculocutaneous flap. LD = latissimus dorsi flap. P = Prosthetic implant

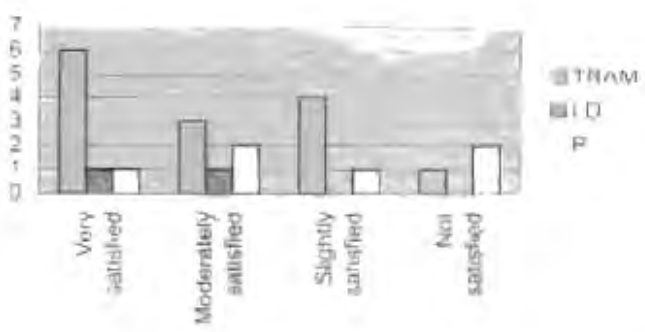


9.3 Self Assessment

Each patient was given the opportunity to score her own cosmetic result. Eight patients were very satisfied (scored 4), 6 moderately satisfied (scored 3), 5 slightly satisfied (scored 2) and 3 not satisfied at all (scored 1). The breakdown of each reconstructive method is summarized in Figure 3.2.

Figure 3.2: Self assessment scoring in each group

TRAM = transverse rectus abdominis musculocutaneous flap. LD = latissimus dorsi flap. P = Prosthetic implant

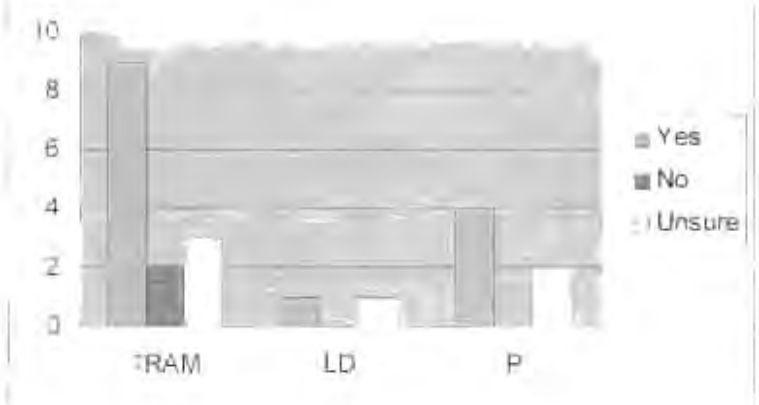


In answering the question whether the patient would recommend the procedure to someone else, 14 answered "yes", 2 answered "no" and 6 were unsure. In the TRAM

flap group 9 patients answered "yes", 2 patients answered "no" and 3 were unsure. In the LD group, 1 patient answered "yes" and the other patient was unsure. In the prosthesis group, 4 patients answered "yes" and 2 patients were unsure. The answers in each of the different reconstructive method groups are illustrated in Figure 3.3

Figure 3.3: The answer to the question whether the patient would recommend the procedure to somebody else.

TRAM = transverse rectus abdominis musculocutaneous flap, LD = latissimus dorsi flap, P = Prosthetic implant



CHAPTER FOUR: Discussion

Breast conservation surgery (BCS) has now been established as a safe treatment option for primary breast cancer according to the National Cancer Institute position statement.[61] Although BCS is the appropriate treatment option for many patients, mastectomy is still indicated when the margin control with wide local excision is a problem or when the patient is unable to attend for post-operative radio therapy. There are also patients who will prefer a mastectomy or patients where a wide local excision may result in a deformity which is unacceptable because of relatively small breasts. For these patients, the technology of breast reconstruction can reverse some of the psychosocial and physical impact of the disfiguring operation of mastectomy.[62]

1 Follow-up after Breast Reconstruction

Numerous follow-up studies had been published after breast reconstruction. In some of these studies 90-100% follow-up rates were obtained.[63] However, in several studies where patients were asked to re-attend a clinic or fill in forms for a postal survey, response rates were as low as 60%. [64.65] Our response rate of only 40% is below average for this type of study. This is probably related to socio-economic factors. Because patients do not have telephones of their own, telephone numbers given on admission are often the telephone numbers of a friend/ employer or neighbour. Because the investigator had to contact people telephonically and arrange a follow-up visit, the number of patients included in this study was directly related to how many patients were contactable and how many of then were willing to come back to the hospital for a follow-up visit. The resulting small sample size impaired the use of statistical methods to interpret the data and the conclusions must therefore be interpreted with this in mind.

2 Systemic Risk Factors taken into consideration for Reconstructive Surgery

2.1 Age

In general there is very little proof that increased age is associated with an increased risk of perioperative complications. In most existing studies, age made no significant difference to the cosmetic outcome of the surgery.[66,67] In a recent study,[68] age has been shown to significantly impact on outcomes. In our current study the mean patient age was 50.2 years. Compared to Woerdeman's study[68], the patients in the current study were older. Because of a general trend for patients at Groote Schuur Hospital to present later with breast cancer than in the developed world, a smaller percentage of young patients present with early breast cancer. Woerdeman reported a higher incidence of mild complications in patients older than 43 years, including seromas or hematomas in the immediate post operative period, and mild wound infections. The aim of the study done at Groote Schuur Hospital was not focussed on immediate post-operative complications. Thus the incidence of mild complications can't be assessed.

The present study shows no significant relationship between age and cosmetic outcome. The choice to have a breast reconstruction procedure rather than a mastectomy alone can unfortunately not be linked to a particular age group, as this option only exists for patients younger than 55 in our hospital. Only two of the 22 patients felt they would not recommend breast reconstruction. Although this is not statistically significant, it is interesting to note that both these patients were 55 when they had the breast reconstruction.

2.2 Body Mass Index

Increased body mass index was associated with a significantly higher total complication rate in the Michigan study. Woerdeman[68] reported a significantly increased risk of losing a prosthetic implant in patients with a body mass index over

$24kg/m^2$. There was also an increased risk for wound dehiscence and ischaemic skin changes.

Interpreting the data of this study, the patients were divided into 2 groups: the first group (5 patients) had a body mass index of < 25. The second group (17 patients) was overweight/obese (body mass index > 25). Because of the small sample size the data was only interpreted by nonparametric tests. The mean score for the first group was 11.6 and for the second group 10.5. Although the difference between the 2 groups was not statistically discernible (p=0.48), cosmetic outcome did show a tendency to be better in the patients where body mass index was below 25.

Breast reconstruction was introduced at Groote Schuur Hospital in 1998. The procedure was initially offered to all patients with early breast cancer under the age of 55 years. Since then our practice has changed. Because cosmetic outcome is not satisfactory in obese patients we are now only offering this procedure in patients with a body mass index under 25.

2.3 Diabetes

Dowden reports that preoperative patient selection may decrease the postoperative implant loss.[69] Not only does he exclude patients with high body mass index and smokers, but he also excludes insulin dependant diabetics. However, in other studies this subgroup of patients is not excluded.[68]

The current study did not include diabetic patients. Of the 22 patients that were followed up, only one had insulin dependant diabetes. Current practice at Groote Schuur Hospital entails offering breast reconstruction to insulin dependant diabetics if they do not show any significant cardiovascular risk factors.

2.4 Cardiovascular Disease

Cardiovascular risk factors constitute some of the main factors in the choice of procedure in breast reconstruction. Because of prolonged anaesthetic, patients with

significant cardiovascular risk factors are generally not offered TRAM flaps. It is the opinion of the author that this correlates well with the literature and current trends regarding choice of cosmetic procedure and cardiovascular risk factors.[68]

In the study current study very few patients (n = 3) had a history of ischaemic heart disease. Patients with significant cardiovascular risk were not selected for breast reconstruction. Current practice at Groote Schuur Hospital has changed and prosthetic implantation is now offered to patients with significant cardiovascular risk factors. With current technology and experienced surgeons, the procedure can now be done in a shorter anaesthetic time, reducing the risk in this group of patients.

2.5 Smoking

It is perceived that certain risk factors such as smoking and obesity can substantially increase the complication rates of breast reconstruction. However, in a large study conducted in Michigan the total complications in a group of smokers was 37% and in a group of non-smokers 47%.[70] There were no association between smoking variables and complication rates (p = 0,28). This is a somewhat surprising finding, bearing in mind that smoking has long been a relative contra-indication to many reconstructive procedures. Higher flap-loss rates, skin slough and wound healing complications has been reported by clinical researchers in the past.[71] Woerdeman[68] reported significant increase in complications in smokers. Accepting a 6,3% chance of loss of implant for an "optimal" patient, they conclude that this risk increased to 32% in a smoker.

In the present study, one of the aims was to look at smoking as a risk factor influencing cosmetic outcome. Taking into account a continuous score amalgamating the scoring in all three different subsets, namely the scoring in the photo assessment, self assessment and objective scoring, smokers had on average a 2.09 units lower score than non smokers. Although this result is not statistically significant (p>0.28), it is probably related to sample size and not a true reflection of the complications seen in smokers.

3 Type of Reconstruction

Prior to breast reconstruction, the patient is normally counselled in terms of surgical options and outcomes. Considering medical fitness for theatre and theatre time, an informed decision is normally made by the patient and attending physician. Personal preferences, advantages and disadvantages are an important part of the decision.

In the group of 22 patients who had SSM, 16 patients had tissue flaps and 6 patients had prosthetic implants. The tissue flaps were either TRAM or LD flaps. The local pratice between 1998 and 2001 was that 60–70% of reconstructions were autogenous tissue reconstructions. Currently substantially more prosthetic implantations are offered. This is mostly related to a lack of theatre time and resources to accommodate long procedures like TRAM flaps.

With respect to cosmetic results, the only statistically significant factor in this study was the choice of reconstructive procedure. Tissue flaps had a far better cosmetic outcome than implants (p=0.01). This outcome was measured by a combined score taking into account the photo assessment, objective score and self assessment score. The average combined score for patients with tissue flaps was 12.75 where the average combined score for patients with prosthetic implants was 7.8 (p=0,01).

A similar study was done by Tonseth et al in Norway.[72] In this study general satisfaction with breast reconstruction was measured with a postal survey questionnaire. Comparing the outcome of deep inferior epigastric perforator (DIEP) flap and expandable breast implant (EBI), the DIEP group of patients were more satisfied with their appearance ($p < 0.0005$), reported improved social relationship, and fewer patients were sad about their body image ($p = 0.01$). Using the same general satisfaction items, Alderman et al found that patients who had TRAM flaps were more satisfied with cosmetic outcome than patients with prostheic implants.[73] Similar results are reported by other researchers evaluating breast reconstruction with breast implant or pedicled TRAM alone.[74]

In conclusion, the evidence from the literature and the findings from the current study would suggest that tissue reconstruction has a better cosmetic outcome than

reconstruction with implants. These preliminary results should now be followed by a larger study including more recent results at Groote Schuur Hospital.

4 Contralateral Breast Management

Unilateral breast reconstruction after mastectomy creates the challenge of providing a natural-appearing, symmetrical breast mound. Ultimately, symmetry and proportion are the most important factors in cosmetic outcome after the reconstructive process. From the onset this is therefore a guiding principle, influencing the choice of reconstuction type, and final decisions regarding nipple and areola placement. Unilateral breast reconstruction is notoriously more challenging and more likely to have asymmetrical results compared with bilateral breast reconstructions. The opposite breast is essentially the key to planning unilateral breast reconstruction.[75]

In an attempt to preserve some degree of symmetry and allow certain reconstructive options, additional procedures were necessary on the contralateral breast in 12 of the 22 patients. This decision was based on the patients' premastectomy breast characteristics and postreconstruction desires. Simple size and shape adjustments were achieved with contralateral breast reduction. In this group of patients nobody received a contralateral breast augmentation although this practice has recently been introduced at Groote Schuur Hospital. Symmetry procedures in the current study, stratified by method of reconstruction, are depicted in Table 4.1.

Table 4.1: Implant versus Autologous Reconstruction: Contralateral Breast Managment

Reconstruction	Reduction	None
Implant	2	4
Autologous	10	6

In the current study reconstructions involving an implant required a symmetry procedure in 33% of the patients, where as autologous tissue reconstruction required it in 62,5%. This does not correlate well with the Losken study,[75] mainly because in the current study augmentation was not offered as an option in the opposite breast. In the

Losken study, 66% of patients receiving an implant had a symmetry procedure, augmentation being the most common (41%). Losken concluded that symmetry procedures were less frequent after autologous tissue reconstruction. However, in the context of the current study the opposite is true.

Relying on a contralateral procedure to maximize aesthetic results is an acceptable practice. The versatility in size and shape of a TRAM flap often allows a woman's large opposite breast to be matched without additional modification. The breast mound achieved with implant reconstruction is less natural and a trend to move to a contralateral implant to achieve symmetry has developed in Groote Schuur Hospital.

Unlike autologous tissue, the implant reconstruction will not change in size with the opposite breast as the patient gains or loses weight. Major changes in breast symmetry over time is more likely with implant reconstructions. This could be a factor in this study, which was done 3 to 5 years post procedure. The ideal time to perform the symmetry procedure remains controversial. It is easier to adjust the opposite breast during the initial reconstruction. On the other hand some surgeons prefer to adjust the contralateral breast at a later stage after the completion of any adjuvant therapy. It is current practice at Groote Schuur to offer the reconstruction and symmetry procedure as a single operation at the same time as the mastectomy.

5 The Influence of Adjuvant Therapy on Cosmetic Results

5.1 Radiotherapy

Although it was not statistically significant, radiotherapy both before and after surgery had a positive association with having at least one complication in the large Michigan study.[76] With regard to quality of life, patient satisfaction and cosmetic outcome after breast reconstruction using DIEP flap or expandable breast implant, a study done in Norway[77] shows that the influence of radiotherapy on cosmetic outcome was not statistically significant. In contrast, a recent study in New York at the Memorial Sloane Kettering Cancer Centre,[78] showed that radiotherapy did influence cosmetic

outcome. Patients who received radiotherapy had a greater chance of having a poor cosmetic result compared with patients who did not receive radiotherapy.

In the current study post-operative radiotherapy was given to 8 patients. Comparing the cosmetic outcome in these patients with the group of patients who did not receive radiotherapy, the results were not found to be statistically discernible ($p=0.66$).

Reviewing the expander/prosthesis group, 3 of our patients (50%) received radiotherapy. In 2 of these patients capsular contracture was present at the time of their follow-up visit and their cosmetic outcome was not favourable. None of the patients who did not receive radiotherapy developed a significant capsular contracture. Radiation history remains a significant predictor of overall aesthetic result.

5.2 Chemotherapy

Only 3 patients in the study group did not receive chemotherapy. Therefore the influence of chemotherapy on cosmetic outcome could not be assessed in this study. Other studies have shown that the influence of chemotherapy on cosmetic outcome is much less significant than radiotherapy. [63,65]

6 Self Esteem and Quality of Life

Among researchers and clinicians, views on patient satisfaction has evolved considerably over the last few years. In the 1950s and 60s patient satisfaction was studied by looking at patient compliance. This sort of research was conducted mainly by sociologists. Today patient satisfaction is becoming increasingly important in clinical care. More research is done on the patient and the patient's expectations. In addition, this research is being conducted by clinicians and surgeons, and not so much by people from outside the discipline.

The present study gives a very superficial view of patient satsifaction. Many psychosocial factors after breast reconstruction have not been examined. It would be

possible to do an in-depth study looking at quality of life in a much more detailed way in the future.

7 Current practices at Groote Schuur Hospital

In South Africa a discrepancy exists between private and state health care. Private health care has become a commodity that can be purchased and sold like most other consumer products. It is a market driven by patient preferences and needs. In contrast to this, the state sector is not yet part of this consumerism. In the state sector patients do not always have the choices that private health care offers and patient need must be weighed up against health care efficiency and cost. Where consumer satisfaction is one of the most important measures of health care in the private sector, the state sector is often not as efficient and competitive and patients' choices do not always play the key role that it should play in health care.

Given the South Afrcan Government sector health care industry's current focus on cost-saving mechanisms and primary health care, and the relative lack of cosmetic surgery funding, studies such as this become important. Studies focusing on patient satisfaction and quality of life in our country should show up the deficiencies in the health care system. For example, it is clear from the current study that autologous flap reconstructions deliver better cosmetic results and patient satisfaction than prosthetic implants. Because of cost constraints and theatre time, Groote Schuur is however offering prosthetic implant as a first choice to many patients.

The major limitation in this system is the fact that Groote Schuur cannot at this stage offe freedom of choice to all breast cancer patients to choose their type of surgery and reconstruction method. Although patient satisfaction is in theory the most important factor determining outcome, the reality in the state sector hospital in South Africa today is having to cope with limited resources and theatre time. Clinicians and surgeons are therefore continuing striving towards offering procedural choice to patients with breast cancer.

CHAPTER FIVE: APPENDIX

Appendix A Photographs

Appendix B Research committee approval

Appendix C Patient Informed Consent Form

Appendix A: Photographs

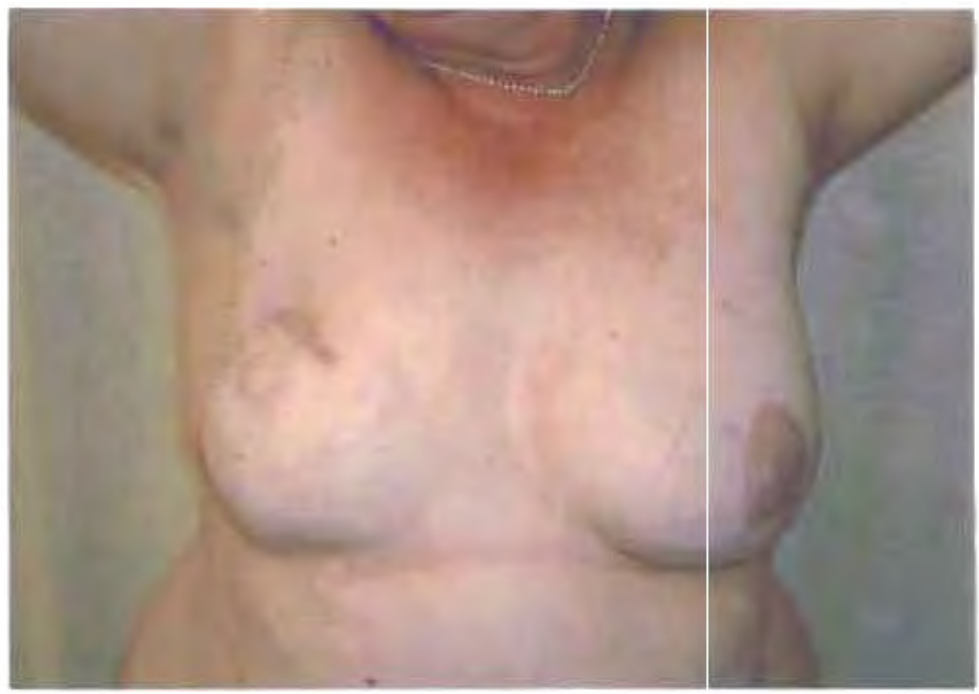
Examples of patients who scored 1 (gross distortion between breasts) in the Photographic Assessment:
Patients who received TRAM flap reconstruction

Examples of patients who scored 1 (gross distortion between breasts) in the Photographic Assessment:
Patients who received Prosthetic implant reconstruction

Examples of patients who scored 2 (obvious difference, but no distortion between breasts) in the Photographic Assessment:
Patients who received TRAM flap Reconstruction

Examples of patients who scored 2 (obvious difference, but no distortion between breasts) in the Photographic Assessment:
Patient who received LD flap Recontruction

Examples of patients who scored 2 (obvious difference, but no distortion between breasts) in the Photographic Assessment:
Patient who received Prosthetic Implant recontruction

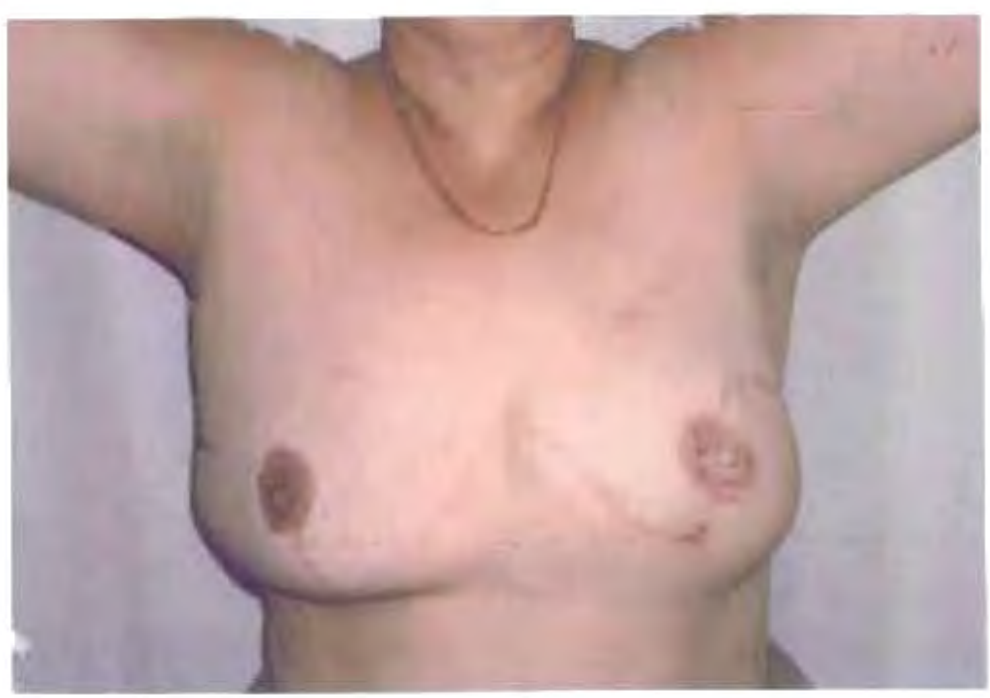


Examples of patients who scored 3 (slight difference between breasts) in the Photographic Assessment:

Patients who received TRAM flap reconstruction

Examples of patients who scored 3 (slight difference between breasts) in the Photographic Assessment:

Patients who received TRAM flap reconstruction



Examples of patients who scored 3 (slight difference between breasts) in the Photographic Assessment:

Patients who received LD flap recontruction

Examples of patients who scored 3 (slight difference between breasts) in the Photographic Assessment:

Patients who received Prosthetic implant reconstruction

Appendix B: Research Committee Approval

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: lamees.emjedi@uct.ac.za

27 September 2007

REC REF: 453/2006

Dr E Muller
Renal & Transplant Unit
GSH

Dear Dr Muller

PROJECT TITLE: SKIN SPARING MASTECTOMY AND IMMEDIATE RECONSTRUCTION FOR BREAST CANCER-A THREE TO FIVE YEAR FOLLOW-UP STUDY OF POST-OPERATIVE PATIENTS LOOKING AT COSMETIC OUTCOME

Thank you for submitting your study to the Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Thank you for re-contacting the participants in your original study.

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

A/PROF. M. BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Appendix C: Patient Informed Consent Form

INFORMED CONSENT

A STUDY OF THE COSMETIC OUTCOME FOLLOWING TOTAL MASTECTOMY AND RECONSTRUCTION FOR BREAST CANCER

You have been approached to participate in this research study. Please read this document carefully and ask any questions you wish

I.....consent to take part in this study as explained to me by Dr Muller

This study looks at the cosmetic outcome of specific surgical treatment for breast cancer. This is the removal of the breast and plastic surgery to reconstruct a new one

This clinical trial has been approved by the University of cape Town Ethics Research Committee.

PATIENT SIGNATURE DATE

PATIENT INFORMED CONSENT

A STUDY OF COSMETIC OUTCOME FOLLOWING TOTAL MASTECTOMY AND RECONSTRUCTION FOR BREAST CANCER

Please read this carefully and ask any questions you wish. You need not take part in the study if you do not want to. If you decide to take part, you can withdraw at any time.

In this study we want to assess patients' satisfaction with their surgery as well as look at the cosmetic outcome of the operation in a more objective way.

To do this we will take photographs of your breast a few years after the operation. We will not photograph your face and your identity will be protected. The photographs will be shown to a scientific panel who will assess them. They may be used for scientific publication, or presentation. We will also take some measurements of your breast and ask your opinion about the appearance of the breast after surgery.

We anticipate that this study will benefit future patients with breast cancer and allow us to advise them better on the outcome of surgery.

Please feel free to ask any questions prior to signing the consent form. We will be available at any time to discuss any queries about the study before, during, and after treatment has been performed.

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