

Risk-reducing, conservative mastectomy – analysis of surgical outcome and quality of life in 272 implant-based reconstructions using TiLoop[®] Bra versus autologous corial flaps

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Background: Different approaches have evolved for conservative mastectomies, mostly according to surgeon's preference. Patients' perspective was not always in the primary focus. BRCA status has drawn much attention and therapeutic as well as prophylactic mastectomies are rising. However, knowledge on quality of life (QoL) thereafter is limited. We investigated the surgical and patient reported outcome of conservative mastectomies with implants and TiLoop[®] Bra *vs.* corial flaps.

Methods: Conservative mastectomies were analyzed from a prospectively maintained database in a unicentric study of consecutive 272 reconstructions from 2000-2014. We used four validated QoL questionnaires: FACT-G, EORTC C-30, EORTC B-23 and Breast Cancer Treatment Outcome Scale (BCTOS). The use of TiLoop[®] Bra, a titanized polypropylene mesh, for lower breast pole coverage was compared to autologous corial flaps.

Results: A total of 217 patients with 272 conservative mastectomies (55 bilateral) were included. Median follow-up was 3.5 years (range, 0-14 years). Skin-sparing mastectomy (SSM) was performed in 131 patients and subcutaneous mastectomy (SCM) in 86 patients. Invasive breast-cancer was the indication for surgery in 106 patients, non-invasive breast cancer (DCIS) in 80 patients, prophylactic indication (BRCA1/2-mutation) in 30 patients and contralateral alignment in 1 patient. TiLoop[®] Bra was used in 78 and corial flap in 79 patients. Response to questionnaires was 70%. TiLoop[®] Bra improved aesthetic results ($P=0.049$) and prevented implant dislocation ($P=0.009$). All patients expressed their adherence to the decision for surgery. Patients with SCM expressed their satisfaction even to a higher extent than those with SSM, particularly with regard to symmetry ($P=0.018$) and scars ($P=0.037$).

Conclusions: QoL after conservative mastectomies is demonstrated as excellent in several validated QoL-instruments. Double-plane technique for coverage of the implant yields good results with autologous corial flaps and TiLoop[®] Bra, favouring the latter in terms of aesthetics and prevention of implant dislocation.

Keywords: TiLoop[®] Bra; corial flap; conservative mastectomy; skin-sparing mastectomy (SSM); subcutaneous mastectomy (SCM); quality of life (QoL)

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Introduction

Breast cancer requires mastectomy in—at least—one out of four women, and the possibility to prevent breast cancer in families with known genetic inheritance by prophylactic surgery increases the demand for this procedure (1,2). If breast conservation (BCT) is not an option, the question arises which type of mastectomy shall be applied. The evolution of surgical techniques for removal of the mammary gland started from Rotter-Halsted's radical mastectomy (3) to Patey's modified mastectomy (4) of the last millennium up to modern concepts with preservation of the skin envelope by skin-sparing mastectomy (SSM), subcutaneous mastectomy (SCM) or nipple-(areola) sparing mastectomy (NSM/NASM) which are considered as oncologically safe (5). Different approaches and incision patterns have been developed for these surgical procedures such as tennis-racket incision pattern, reduction mammoplasty technique as inverted T- or J-incision, up to total or partial periareolar incision. These techniques have been applied mostly according to the surgeons' preference. The patients' perspective was not always in the primary focus. BRCA-mutational status has attracted much attention in the last years when individuals of public interest submitted themselves to prophylactic mastectomy in cases of a positive BRCA1/2-mutational status (1). We investigated the patient's view on these procedures with validated measurements of quality of life (QoL) and explored the surgical safety and acceptance of these surgical procedures.

Patients and methods

A consecutive cohort of a prospectively maintained database in a single-institution experience at European Breast Center Düsseldorf was analyzed for this study. All patients were eligible who were treated with an immediate implant-reconstruction after mastectomy for prophylactic and therapeutic indications between 2000 and 2014. Inclusion criteria were infeasibility of BCT and no necessity of post-mastectomy radiation as by pre-surgical assessment. Exclusion criteria were inflammatory breast cancer, skin infiltration/fixation and previous radiation. All autologous reconstructions were excluded from this study. Data was retrieved from patient charts and multiple detailed questionnaires. We used four validated QoL-questionnaires to evaluate patients reported outcome (PRO) and QoL: EORTC C-30 (6), EORTC B-23 (7), FACT-G (8) and Breast Cancer Treatment Outcome Scale (BCTOS) (9) and also

a customized, study-specific questionnaire. Questionnaires were repeatedly sent by regular mail (thrice). We analyzed the surgical outcome with regard to the safety and the complication of the methods, as well as PRO regarding the volume, symmetry and aesthetic result including the evaluation of scars. Early complications were defined as first presentation of sequelae before 6 months after surgery and late complications as occurring beyond 6 months after surgery. In particular, we compared the use of a TiLoop® Bra for coverage of the lower pole of the breast with the coverage of the same region with an autologous corial fat flap. This study was approved by the Institutional Review Board (IRB) and complied with the declaration of Helsinki.

Reconstruction techniques

Reconstruction mode 1: technique developed for normal breast size (non-ptotic)—coverage with a titanized polypropylene mesh (TiLoop® Bra) (Figure 1A-C)

The glandular tissue is removed via a reduction mammoplasty pattern and the *Musculus pectoralis* (*M. pectoralis*) major incised at its insertion and with cautious mobilisation of the *M. serratus* in the lateral part and the titanized mesh is sutured to the edge of the *M. pectoralis* major to cover the lower pole and wrapped around the implant without attaching it to the chest wall (double-plane).

Reconstruction mode 2: technique developed for hypertrophic and ptotic breasts—coverage with a corial-fat flap (Figure 2A-C)

Initially, when the skin incision is performed in the sense of a reduction mammoplasty (inverted T), the skin of the lower hemisphere of the breast is de-epithelialized and the corium is separated from the glandula. The glandular tissue is removed and the *M. pectoralis* major incised at its insertion and a subpectoral pouch has been formed with cautious mobilisation of the *M. serratus* in the lateral part. The corial flap is then sutured to the edge of the *M. pectoralis* major to cover the lower pole of the implant (double-plane).

Results

We included 217 patients with 272 mastectomies (55 bilateral cases) and immediate breast reconstructions (IBR) in our study. Median follow-up was 3.5 years (range, 0-14 years). SSM was the most frequently performed procedure with 131 patients, whereas SCM was performed in 86 patients.

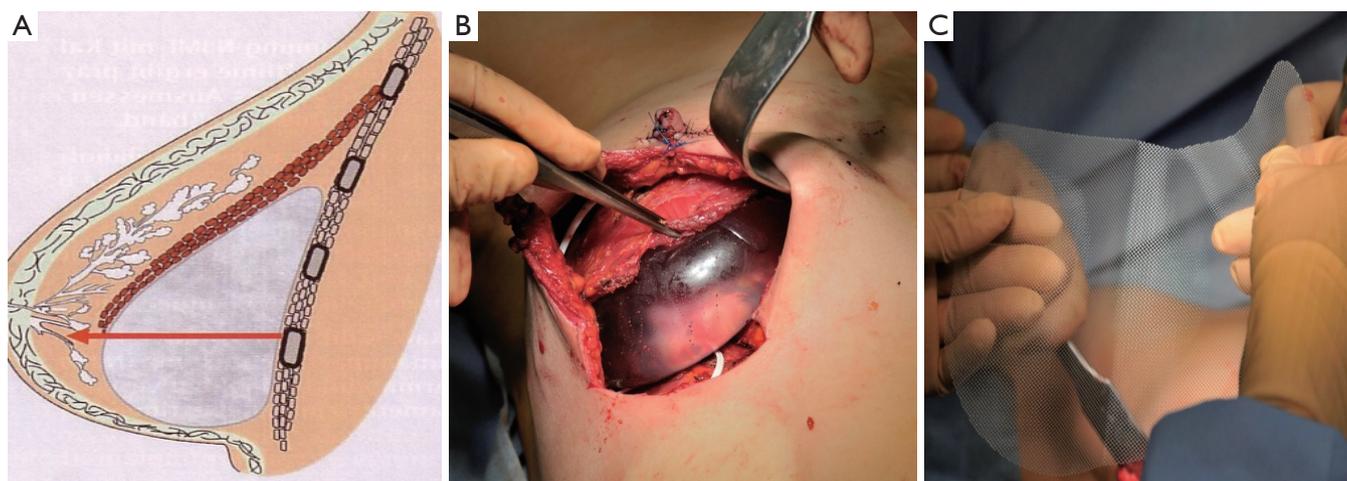


Figure 1 Coverage of the lower implant pole with a titanized polypropylene mesh. (A) Lateral projection; (B) edge of musculus pectoralis (M. pectoralis); (C) titanized polypropylene mesh.



Figure 2 Coverage of the lower implant pole with a corial-fat flap. (A) Reverse side—corial flap; (B) outer side—corial flap; (C) corial flap at musculus pectoralis (M. pectoralis).

Invasive breast-cancer was the indication for surgery in 106 patients, non-invasive breast cancer (DCIS) in 80 patients, prophylactic indication (BRCA1/2-mutation) in 30 patients and contralateral alignment in 1 patient. Comparing the two groups of coverage of the lower pole of the implant, groups were well balanced with 78 patients with a titanized, polypropylene mesh TiLoop® Bra and 79 cases with a corial fat flap. For evaluation of patient reported outcome, we were able to refer to a final questionnaire response rate of 70%.

Sequelae of surgery

Early complications

Early complications—defined as surgical sequelae occurring

before 6 months after surgery—were low in our cohort: We registered 6 scar insufficiencies, 7 infections, 10 seroma, and 17 hematomas with the necessity of a wound revision. Seventeen patients had hypertrophic scars (keloid). A comparably frequent complication was the loss of sensitivity in any part of the breast or dysaesthesia, reported by 78 patients, which was due to skin incisions.

Late complications

Late complications were low in our cohort: 15 patients developed a capsula fibrosis. In none of these cases implant loss occurred. We recorded an implant rotation in three cases which did not necessitate surgery again. Seven patients reported any kind of dislocation of the implant. There was a significant correlation with the occurrence of an implant

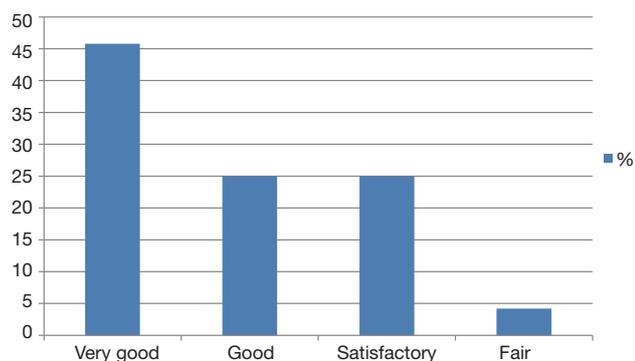


Figure 3 Satisfaction with symmetry after conservative mastectomy.

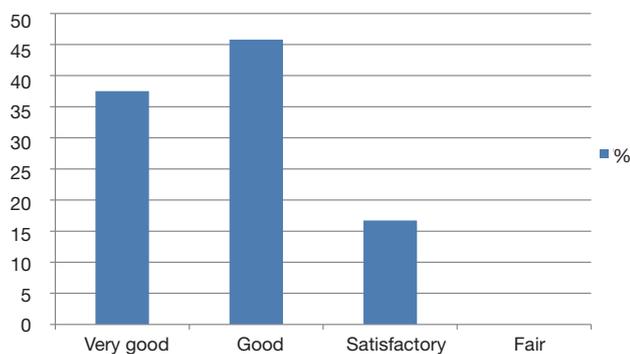


Figure 4 Satisfaction with volume after conservative mastectomy.

dislocation and the mode of coverage of the lower pole of the implant: all implant dislocations occurred in the group of corial-fat flaps, and none in the group of TiLoop® Bra meshes ($P=0.01$).

A rupture of implants was seen in one case only. A removal of implants was necessary in two cases. An exchange of implants was performed in 17 cases. Restrictions of movement were denoted by 22 patients and only six recurrences were seen in this large cohort.

Symmetry

Patients were satisfied with symmetry after both SSM/SCM and immediate reconstruction, even though the reconstruction of the contralateral side was eventually performed as a two-point time procedure. As much as 45.8% rated the symmetry as very good, 25% as good and 25% as satisfactory. Thus, almost 96% of patients were satisfied with the symmetric result of the procedure; only 4.2% rated the result as “fair” (Figure 3). Patient reported outcome was best when the procedure was performed bilaterally ($P=0.007$).

Volume

Satisfaction with volume was high with 37.5% rating “very good”, 45.8% as “good” and 16.7% as “satisfactory”. Thus all patients were satisfied with reconstruction volume (Figure 4).

Adherence to the decision

All patients in the corial-flap group and all patients in the TiLoop® Bra group considered the operation as the right choice and thus demonstrated adherence to the decision for this type of surgery.

Influencing factors on overall aesthetic result

We found a significant improvement by use of titanized polypropylen meshes in the aesthetic results ($P=0.049$) as well as in the prevention of implant dislocation ($P=0.009$).

Patients with SCM expressed their satisfaction even to a higher extent than those with SSM. This referred particularly to satisfaction with symmetry ($P=0.018$) and satisfaction with scars ($P=0.037$).

Of note, genetic screening for BRCA1/2 mutation did not have an impact on partner interaction ($P=0.200$). Interestingly, radiotherapy—performed in 23 patients—was neither detrimental on cosmetic outcome ($P=0.754$) nor on body image ($P=0.660$). Smoking, however, was associated with a significant deterioration of the aesthetic outcome ($P=0.007$).

Quality of life (QoL) and implant reconstruction mode

QoL was good after both SSM and SCM, and rating of the result was best when the procedure was performed bilaterally. There was no difference in QoL depending on the use of either corial-flap or mesh-reconstruction ($P=0.757$), also no significant difference in perception of pain after surgery ($P=0.237$) with either of the two modes of coverage of the lower breast pole, however—as stated above—implant rotation and displacement was less often when meshes were used, which influences QoL strongly.

Discussion

This study provides evidence on the surgical outcome and the patient reported QoL after risk reducing surgery of the breast with SSM and SCM. In our study, we analyzed skin-sparing and subcutaneous mastectomies, all combined with

immediate BR and evaluated both the physical as well as the psychological well-being after these surgical procedures. This is of major importance, as the demand for this type of surgery increases. As a recent publication indicated referrals to genetics services showed a rise from May 2013 onwards, with almost 2.5-fold quantity, in a consortium of over 30 UK breast cancer family history clinics and ten more genetics centres, when film actress Angelina Jolie decided to make public that she underwent BRCA testing and subsequent prophylactic mastectomy and salpingo-oophorectomy. This trend was perceived world-wide and is apparently long-lasting (1).

Quality of life (QoL) instruments

To analyze QoL and surgical outcome after these surgical procedures, as much as 272 reconstructions in 217 patients were analyzed retrieving data from patient charts, customized questionnaires and validated instruments of measurement of QoL in our study.

So far, these surgical procedures have not been evaluated with several QoL instruments at a time: We used EORTC C-30 (6), EORTC-BR23 (7), FACT-G (8) and BCTOS (9). These instruments focus on the self-reporting of patients concerning the following items: functional restrictions, disease symptoms, and global perception of QoL. For validation of surgical techniques by patients, BCTOS has been demonstrated to be a reliable instrument for functional and aesthetic assessment (9). Kanatas *et al.* also described these instruments as validated instruments of measuring QoL specifically for breast cancer patients (10). Furthermore, we developed a study-specific questionnaire which was comparable to similar studies (11,12). The design of our customized questionnaire put emphasis on individually perceived QoL under distress of the risk of breast cancer as well as measurements of surgical outcomes. We were able to retrieve information of these questionnaires by as much as 70% of all patients with three emissions by regular mail.

Breast cancer is a threat to life of patients, and the primary aim of breast cancer therapy is the risk reduction by local and systemic treatment. However, the side effects of either of the therapies affect the physical and psychological well-being of the patients. With views on the surgical therapy, surgeons need to be aware of the best surgical options for their patients and their physical and psychological effects. Physical, psychological and social well-being builds the dimensions of QoL and all

three refer to each other (13). Psychological well-being is deteriorated massively by the diagnosis of breast cancer as every individual is confronted with the anticipated risk of mortality. When the probability of survival is higher, aspects of an unimpaired body image regain importance as the breast is a symbol of female identity and sexual attraction. Chen *et al.* (14) performed a systematic literature review to identify breast-surgery-specific PRO measures and reported significant shortcomings in terms of formal development and psychometric evaluation.

A systematic review conducted by Pusic *et al.* (15) found that only 1 out of 223 PRO measures used in breast surgery studies had psychometric evidence to support their use in the breast cancer population. The reviews by Chen *et al.* (14) and Pusic *et al.* (15) are limited to breast cancer surgery-specific instruments. We included both breast-cancer-surgery specific and general instruments of measurement of QoL.

The techniques analyzed in this study, subcutaneous and SSM and the latter with two different modes of coverage of the lower breast pole were examined with detailed questionnaires.

Patients satisfaction, body image

We detected a high grade of patient satisfaction with volume (99.8%), symmetry (96%) and scars in both forms of mastectomy and immediate reconstruction. Ueda *et al.* (16) found a smaller cohort of 74 patients that the median score for patient satisfaction including social activity, physical aspects and general condition, were the same in the three groups of BCT, mastectomy and mastectomy with immediate reconstruction. For body image however, BCS and IBR scored higher than with mastectomy only ($P < 0.05$). Ueda's study group included a scoring by four external reviewers for cosmetic outcome—which we did not apply to our study population to avoid subjective bias—and there was no difference in the estimated cosmetic outcome between BCT and IBR ($P = 0.20$) nor between the SSM and NSM subgroups ($P = 0.09$). Scores referring to pain perception and sexuality were better in the BCT than in the mastectomy group; however there was no difference between BCT and IBR regarding these items.

Adherence to decision and body image after surgery

We focussed primarily on satisfaction and QoL with SCM and SSM, and particularly on the mode of reconstruction of the lower pole of the breast in skin sparing mastectomy, with

and without the use of meshes and corial flaps. So far, this item was not analyzed in a direct comparison in literature. All patients of our study expressed their conviction from the aesthetical viewpoint that this type of surgery was the right decision (100% adherence to the decision). The majority of patients rated their satisfaction with symmetry, volume and scars with “good” and “very good”.

We detected a higher satisfaction in patients with reconstructions which were performed bilaterally. Nano *et al.* (17) analyzed the psychological impact and cosmetic outcome in 123 BR compared with 109 BCT and 78 mastectomies. QoL was similar in all groups, but the BCT group and patients with reconstruction had higher body image scores than patients with a mastectomy. Patient satisfaction was higher in the reconstruction group than the breast conservation group, while aesthetic outcome was similar in both groups. The authors concluded that the high satisfaction and cosmesis scores in the BR group were indicating the superior results that can be achieved with BR.

Corial flap

A study with a lower caseload of 27 patients (34 reconstructions) with mastectomy according to a modified Wise pattern with a tissue expander also used a fasciocutaneous flap for coverage of the lower pole of the breast in women with macromastia while the upper part of the breast was covered by the M. pectoralis major (18). The authors reported a fairly high unplanned re-operation rate of 15%, rate of post-surgical complications of 37%, including seroma of 18% which we did not see in our study. Ladizinsky *et al.* (19) report on a cohort of 60 patients with a de-epithelialized corial flap with a complication rate of 24% (i.e., skin necrosis, hematoma and infection) and analyzed risk factors for these events and found that overall complications were associated with a body mass index (BMI) greater than 35 ($P=0.035$) and prior smoking ($P=0.0001$). The most frequent complication in their study was mastectomy flap skin necrosis (30%). This correlated with placement of a permanent implant ($P=0.029$) and any history of smoking ($P=0.0001$). Skin necrosis led to implant loss in 1.2% in their study. In our study, we did not detect a correlation between implant loss and BMI ($P=0.262$) or history of smoking ($P=0.363$), however we detected that a higher BMI was a predictor for skin dehiscence (without implant loss) ($P=0.043$) whereas smoking exerted a negative impact on aesthetic outcome ($P=0.007$).

TiLoop® Bra

A recent study with a smaller cohort of 34 TiLoop® Bra meshes in the submuscular pocket than in our study compared this surgical approach with 39 TiLoop® Bra meshes with a prepectoral use (20). In their cohort, complications were very low, with two skin flap infections and one wound dehiscence only. No implant loss was recorded. The study group found that TiLoop® Bra was safe and effective in a short-term analysis, both for a retropectoral and a totally subcutaneous implant placement. Contrary to our study, follow-up of this study however was short with 13 months (range, 3-27 months) in the group of TiLoop® Bra mesh, whereas our study had a longer follow-up 3.5 years (range, 0-13 years). Also, inclusion criteria were strict in this study with normal BMI, no large and very ptotic breasts, no history of smoking, no diabetes, and no previous radiotherapy. In our study, we included all patients of any BMI, with large and ptotic breasts, smokers and patients with diabetes, however radiotherapy was allowed after, but also not before surgery. On this background, complication rates were low with no implant loss in the TiLoop® Bra group and only 7 infections, 6 scar insufficiencies, 10 seroma and 17 hematomas in this large cohort of 272 reconstructions. Casella's study did not report on dysaesthesia which we recorded in our study: 78 patients declared to have experienced these sequelae.

Limitations of our study were that we did not randomize patients to each of the modes of reconstruction—like almost all other studies related to breast surgery—but used size and ptosis as criteria to choose the respective method. Questionnaires were sent to the patients by our own institution, however participation was voluntarily and patients were already discharged from hospital and no influence was exerted on the patients.

Conclusions

In our study, we saw the highest scores for aesthetic results in patient reported outcome with the use of titanized polypropylene meshes (TiLoop® Bra) compared with corial flap which was significantly differing. QoL in general was good in both modes of reconstruction and coverage of the lower breast pole.

We found a significant improvement by use of titanized polypropylene meshes in the aesthetic results as well as in the prevention of implant dislocation. All patients expressed their adherence to the decision for this type of surgery, with

highest score with SCM, particularly to satisfaction with symmetry with scars.

Genetic screening for BRCA1/2 mutation did not have an impact on partner interaction and radiotherapy was neither detrimental on cosmetic outcome nor on body image. Smoking, however, was associated with a significant deterioration of the aesthetic outcome.

Dual-plane reconstruction with TiLoop® Bra in normal breasts size and corial flaps in ptotic breasts produces stable results with low complication rates and high levels of QoL in conservative mastectomies.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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