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## Clinical results and patient-reported outcomes in breast reconstructive surgery

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# Summary

The treatment of breast cancer is a substantial part of modern health-care. Fortunately, mortality rates are declining and secondary outcomes including patient satisfaction and cosmetic result gain importance. In this thesis we investigated safety, patient-reported outcomes (PROMS) and aesthetic results after implant-based breast reconstruction (IBBR) and breast-conserving therapy (BCT) to improve these outcomes after reconstructive surgery for breast cancer and a contralateral (CPM) or bilateral (BPM) prophylactic mastectomy.

In chapter 2 the patient satisfaction in one of the largest series of patients treated with ADM-assisted breast reconstruction was assessed by inviting 541 women to fill out a validated questionnaire, the BREAST-Q. A total of 208 (38.4%) patients responded and reported a high satisfaction with after their surgery. A significant decrease in patient satisfaction was noted after unilateral reconstructions for oncological reasons and in patients with a complicated course. The importance of a woman's breast for her psychosocial and sexual functioning was seen in the high correlations between the domains satisfaction with breasts, satisfaction with outcome, psychosocial well-being and sexual well-being ( $r \geq 0.665$ ,  $p < 0.001$ ). In chapter 3 the first study reporting on surgical outcomes and patient satisfaction in one-stage IBBR with a porcine ADM, EGIS, was described. Eighty-four patients were included and a high response rate (81%) was achieved. A low explantation rate of 6.0% was noted and satisfaction with breast ( $59.0 \pm 14.5$ ) and outcome ( $71.2 \pm 19.6$ ) were good.

In chapter 4 the safety of one-stage IBBR with an acellular dermal matrix (ADM) was compared to the conventional two-stage IBBR in the open-label, randomised controlled Breast Reconstruction In One Stage (BRIOS) study. In total, 59 patients (91 reconstructions) were included in the one-stage IBBR with ADM group and 62 patients (92) breasts in the two-stage group. One-stage IBBR with ADM was associated with significant more surgical complications (crude odds ratio 3.81, 95% CI 2.67-5.43,  $p < 0.001$ ), reoperations (3.38, 2.10-5.45,  $p < 0.001$ ), and removal of implant, ADM, or

both (8.80, 8.24-9.40,  $p < 0.001$ ) than two-stage IBBR. No risk factors were identified which explained the difference in complication rate between the two groups.

To understand which factors contributed to the occurrence of this high complication rate in the one-stage group, we examined the one-stage IBBR with ADM group in detail, as reported in chapter 5. Only patients with a one-stage IBBR with ADM reconstruction were selected, and breast size was identified as a significant predictor of adverse outcomes. Younger patients receiving adjuvant chemotherapy were re-operated more frequently. A significant effect of timing of surgery on complication rate, indicating a possible learning curve, was not identified.

The BREAST-Q was used to measure the health-related quality of life at least one year after placement of the definitive implant, to determine if the one-stage IBBR with ADM would result in higher patient satisfaction compared to the two-stage group. The aesthetic outcome was assessed independently by five plastic surgeons based on pre- and postoperative photographs. The scores of all BREAST-Q domains were similar for both the one-stage and two-stage group, as is demonstrated in chapter 6, with a mean Satisfaction with Breasts of  $63.4 \pm 15.8$  in the one-stage group vs.  $60.3 \pm 15.4$  in the two-stage group ( $p = 0.35$ ). The plastic surgeons also gave similar scores to the aesthetic outcome of both methods, respectively  $6.2 \pm 1.6$  in the one-stage and  $6.2 \pm 0.9$  in the two-stage group. A low correlation between the patient-reported outcomes and the surgeon's aesthetic scores were seen, implicating that these are two different things.

To determine the cost-effectiveness of both procedures, the direct costs (in euros) at an institutional level were estimated and compared in chapter 7. The advantage of using an ADM to facilitate a reconstruction in one-stage was thought to result in lower costs. One-stage IBBR with ADM was however associated with extended operation time for both unilateral ( $2.52 \pm 0.55$  vs.  $2.02 \pm 0.35$  hours,  $p < 0.001$ ) and bilateral ( $4.03 \pm 1.00$  vs.  $3.25 \pm 0.58$  hours,  $p = 0.017$ ) reconstructions compared to two-stage IBBR. On top of that, the ADM itself is relative expensive and more complications were seen in the one-stage group. Therefore, the cost-reduction by performing only one operation in the one-stage IBBR with ADM group did not outweigh the total costs of the two-stage IBBR group. Costs were higher for unilateral (€ 11,752 (95% CI € 9987; € 13,611) vs € 9000 (€ 8551; € 9479),  $p = 0.008$ ) and

bilateral (€ 16,714 (€ 14,909; € 18,971) vs € 13,061 (€ 12039; € 14233,  $p = 0.001$ ) one-stage IBBR, with no difference in postoperative health-status between the groups.

The patient satisfaction and cosmetic outcome after breast conserving therapy (BCT) was assessed in chapter 8. In total, 128 patients with T1-T2 breast cancer completed a questionnaire and a significant decrease in satisfaction and cosmetic outcome during the first three years after surgery was seen. The correlation between the reported satisfaction and cosmetic outcome was strongly positive. The cosmetic outcome was mainly influenced by shape, while satisfaction was determined by the appearance of the scar and breast firmness. Younger age and large excision volumes were identified as most significant factors for a poor cosmesis.

The cosmetic outcome of 109 patients after BCT was assessed by 4 reconstructive surgeons in chapter 9. The mean cosmetic outcome was rated as fair (2.7/4.0, SD 0.9, 1.0-4.0), with larger breast size, larger tumour, and axillary lymph node dissection (ALND) as risk factors for a poor cosmesis. The surgeons mainly recommended flap reconstruction and lipofilling of the operated breast in the majority of the cases (55.6% and 94.5% of patients with good and poor cosmesis). A contralateral breast reduction was recommended in respectively 16.7% and 73.3%. The assessment of the cosmesis yielded comparable results, but a strong disagreement between the surgeons regarding the reconstruction technique was present and the development of an algorithm to determine the optimal method for revision surgery after BCT was not possible.